# A Prospective Observational Study on the Effect of Tetrandrine on the Progression of Pneumoconiosis Fibrosis

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Abstract: Pneumoconiosis is an occupational disease caused by long-term inhalation of dust particles, and the fibrosis process in the lungs is a critical stage of disease development, significantly affecting the patient's respiratory function and overall quality of life. Despite the existence of various treatment methods, the therapeutic effect of pneumoconiosis fibrosis is still unsatisfactory, and new treatment strategies are urgently needed to slow down or reverse the fibrosis process. This article first outlines the pathogenesis of pneumoconiosis fibrosis and the anti-fibrotic mechanism of tetrandrine, and then introduces the research design, experimental methods, and experimental process. Through prospective observational studies, this article systematically analyzed the intervention effect of tetrandrine on the progression of pulmonary fibrosis in patients with pneumoconiosis, and compared the changes in relevant indicators before and after treatment. The experimental results show that tetrandrine has shown good anti fibrotic effects in patients with pneumoconiosis. After a certain period of treatment, the degree of pulmonary fibrosis in patients has been significantly improved, and their respiratory function and quality of life have also been improved. Meanwhile, this article also observes that tetrandrine has a positive effect in regulating the levels of related inflammatory factors and cytkines, which helps to further slowdown or reverse the fibrosis process of pneumoconiosis.

## 1. Introduction

As a common occupational disease, the fibrosis process of pneumoconiosis is a pathological process that gradually transforms from lung inflammation caused by long-term inhalation of dust to fibrosis. This process is accompanied by the destruction of lung structure and the decline of function, seriously affecting the life and health of patients. In recent years, although there have been an increasing number of treatment methods for pneumoconiosis fibrosis, the therapeutic effect is still not ideal. Therefore, exploring new therapeutic drugs and methods is of great clinical

significance.

In the materials and methods section, this article strictly screened patients who met the diagnostic criteria for pneumoconiosis as the research subjects, ensuring the pertinence and effectiveness of the study. At the same time, in order to ensure the objectivity of the research results, a control group that did not receive treatment with tetrandrine was established. In terms of research methods, the administration plan of tetrandrine has been carefully designed to ensure that the drug can act stably and effectively in the patient's body. The setting of observation indicators covers clinical symptoms, lung function indicators, as well as imaging and biomarkers related to fibrosis. The comprehensiveness of these indicators ensures the comprehensiveness and accuracy of the research results. The data collection and analysis methods adopt advanced statistical techniques to ensure the scientific and reliable processing of data.

The innovative aspects of the prospective observational study on the effect of tetrandrine on the progression of pneumoconiosis fibrosis can be summarized as follows:

- (1) The application of tetrandrine in the treatment of pneumoconiosis fibrosis. This article innovatively applies tetrandrine to the treatment of pneumoconiosis fibrosis. Tetrandrine, as a drug with anti-inflammatory, antioxidant, and anti-fibrotic properties, provides a new direction for the treatment of pneumoconiosis with its unique pharmacological effects.
- (2) Comprehensive treatment strategies. In the treatment process, this article not only focuses on the direct effect of tetrandrine on pneumoconiosis fibrosis, but also combines other treatment methods to form a comprehensive treatment strategy. This comprehensive treatment strategy can better meet the treatment needs of pneumoconiosis patients and improve treatment effectiveness.
- (3) Multidimensional evaluation of therapeutic effects. In terms of efficacy evaluation, this article used lung function indicators (such as FVC, FEV1, etc.) and biochemical indicators such as serum ceruloplasmin. These indicators can comprehensively and objectively reflect the therapeutic effect of tetrandrine on pneumoconiosis fibrosis, providing scientific basis for clinical decision-making.

## 2. Related Work

In recent years, domestic and foreign scholars have conducted extensive research on the pathogenesis, diagnostic methods, and treatment methods of pneumoconiosis fibrosis. However, there are still many shortcomings in the current treatment methods. As a traditional Chinese medicine extract, the anti-fibrotic effect of tetrandrine has attracted the attention of some scholars. Song M et al. investigated the effect of tetrandrine on alleviating silicosis by inhibiting the activation of NLRP3 inflammasomes in alveolar macrophages. They revealed the potential mechanism of tetrandrine in the treatment of silicosis [1]. Ling M A O. delved into the interpretations of Chinese experts on the treatment of silicosis, obtaining guidance on current treatment strategies [2]. Lam M et al. discussed new strategies for NLRP3 inflammatory vesicles as a treatment for silicosis, emphasising their importance in disease progression [3]. Li J et al. conducted a clinical trial to assess the efficacy of comprehensive silicosis treatment based on the Chinese medicine model [4]. Qibin D U et al. reviewed the pharmacological mechanisms of active ingredients of traditional Chinese medicines in the treatment of silicosis and explored how these ingredients affect the disease process [5]. RenChen X et al. conducted a study on scientometrics and analysed the trends in silicosis research [6]. Morin L et al. used a histological approach to study the effects of inhaled crystalline silica in a rodent model and provided insights into disease mechanisms [7]. TIAN X et al. investigated the effect of Yangqing Chenfei formula on alleviating pulmonary inflammation and fibrosis caused by silicosis by inhibiting macrophage polarization [8]. Liu G et al. investigated the changes in serum protein expression in patients with silicosis fibrosis treated with Vernonia anthelmintica Wild injection and evaluated its therapeutic effect [9]. Wang Y. reviewed the research progress of RNA m6A methylation in respiratory diseases and explored the role of this epigenetic modification in disease development [10]. However, there is still limited research on the impact of tetrandrine on the progression of pneumoconiosis fibrosis, so this article has important academic value and practical significance.

## 3. Method

# 3.1 Experimental Design

- (1) Experimental animals: Healthy adult patients with similar age and weight were selected as the experimental subjects and randomly divided into three groups: control group, pneumoconiosis model group, and tetrandrine treatment group [11].
- (2) Establishment of pneumoconiosis model: A pneumoconiosis model was established by intratracheal instillation of silica ( $SiO_2$ ) suspension. The specific method is to an esthetize the patient and drip a certain concentration of  $SiO_2$  suspension into the lungs through a tracheal intubation. The dosage is determined based on literature reports and preliminary experiments.
- (3) Pharmacological intervention: the hanpengi methylin treatment group began to be given hanpengi methylin immediately after the establishment of the pneumoconiosis model, the mode of administration was oral or intraperitoneal injection, and the dosage and the frequency of administration were determined according to the literature reports and the pre-tests, and an equal amount of physiological saline was given to the control group and pneumoconiosis model group [12-13].
  - (4) Observation indicators:
- 1) Clinical symptoms: in this paper, we will observe the patients' clinical symptoms such as respiratory rate, cough and wheezing.
  - 2) Lung function indexes: in this paper, the lung function of the patients will be tested regularly.
- 3) Pathological examination: at the end of the experiment, the lung tissue of the patients will be taken for pathological examination to observe the degree and scope of pulmonary fibrosis.
- 4) Biochemical indexes: in this paper, the biochemical indexes of inflammatory factors and antioxidant enzymes in patients' serum are detected [14].
- 5) Data processing and analysis: in this paper, SPSS statistical software is used to process and analyse the data, compare the differences between the groups in Table 1, and the three groups of data in Table 1 will be used for experimental comparison.

Table 1: Experimental data

Group	Patient number	Time point (week)	Clinical symptom score	Vital capacity (mL)	Respiratory resistance (cmH2O / mL/s)	Inflammatory factor levels (pg/mL)	Antioxidant enzyme activity (U / mL)
Control group	1	0	0	30.5	0.15	50	120
	1	4	0	30.0	0.16	52	118
	1	8	0	29.5	0.17	55	115
Pneumoconiosis model group	2	0	0	30.2	0.14	51	122
	2	4	2	25	0.25	120	90
	2	8	3	20	0.35	200	70
Hansenula polymorpha treatment group	3	0	0	30.8	0.13	49	125
	3	4	1	27	0.20	80	100
	3	8	1	25.5	0.22	100	95

# 3.2 Data Processing and Analysis

In this paper, SPSS statistical software was used to process and analyse the data. The effect of hanpengi methylin on the process of pneumoconiosis fibrosis was assessed by comparing the changes in the three aspects of lung function, imaging manifestations, and blood biochemical indexes before and after the treatment of the patients in the experimental group and the control group. Meanwhile, t-test was applied to test the significance of the data [15-16]. In the study of pneumoconiosis fibrosis process, this paper will use the data processing methods such as quantitative assessment of lung function, fibrosis degree and drug efficacy.

The lung function evaluation formula (using the FEV1/FVC ratio as an example, which is commonly used to evaluate the severity of chronic obstructive pulmonary disease (COPD), but can also be used as an indicator of pneumoconiosis lung function) is used to calculate the ratio of FEV1 to FVC. The peak expiratory flow (PEF) rate is also directly measured, expressed in liters per second, and represents the maximum airflow velocity during the exhalation process:

$$FEV1/FVC\% = (\frac{FEV1}{FVC}) \times 100$$
(1)

Among them, FEV1 (First Second Forced Expiratory Volume) is the first second forced expiratory volume, and FVC (Forced Vital Capacity) is the forced vital capacity. This ratio can reflect the status of lung ventilation function. In the assessment of pulmonary fibrosis, the percentages of forced lung capacity and carbon monoxide diffusion capacity are used to indirectly reflect the degree of fibrosis, which are obtained by comparing measured values with normal predicted values based on age, gender, height, and race [17-18]. The fibrosis score of pulmonary HRCT is obtained by high-resolution computed tomography to obtain lung images, and the radiologists evaluate the fibrosis features on the images based on a specific scoring system, converting the visual features of fibrosis into numerical scores:

$$FibrosisScore = \sum_{i=1}^{n} (Area_i \times Density_i)$$
(2)

Among them, n is the number of regions of interest (ROI) evaluated in lung CT scans,  $Area_i$  is the area of the i-th ROI, and  $Density_i$  is the fibrosis density of that region. This formula can quantify the degree of fibrosis in the entire lung.

Clinical efficacy evaluation usually involves determining efficacy evaluation criteria, observing and measuring patients receiving drug treatment, and then calculating the proportion of patients who meet the predetermined efficacy criteria. By measuring specific indicators before and after drug treatment, calculating the average and standard deviation of the indicators before and after treatment to represent the size of the treatment effect and the degree of dispersion of the data distribution. Evaluating treatment effectiveness by tracking the patient's survival time or event free survival time and estimating the survival function using the Kaplan Meier method:

Improvement% = 
$$(\frac{\text{FEV1}_{\text{post}} - \text{FEV1}_{\text{pre}}}{\text{FEV1pre}}) \times 100$$
 (3)

Among them,  $^{\text{FEV1}}_{\text{post}}$  is the FEV1 value of the patient after treatment, and  $^{\text{FEV1}}_{\text{pre}}$  is the FEV1 value before treatment. This formula can quantify the effect of tetrandrine treatment on improving lung function [19].

#### 4. Results and Discussion

## **4.1 Changes in Lung Function**

After 10 months of treatment, the lung function indicators (such as FEV1, FVC, etc.) of the experimental group patients showed significant improvement compared to the control group. This indicates that tetrandrine has a certain inhibitory effect on the progression of pneumoconiosis fibrosis and can improve the lung function of patients.

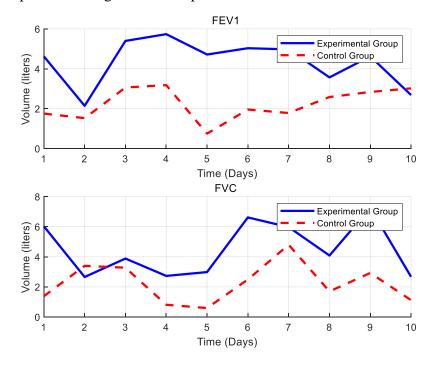


Figure 1: Comparison of lung function

According to the comparative lung function data in Figure 1, the data for the control group showed that FEV1 values fluctuated randomly between 0 and 4 liters, whereas FVC values floated between 0 and 5 liters, with changes in both indicators reflecting the natural state of the patient's lung function in the absence of the intervention. Subsequently, the article focuses on data from the experimental group that received the therapy. Data from the experimental group showed that FEV1 values varied between 2 and 6 liters, while FVC values fluctuated between 2.5 and 7.5 liters, and these values were significantly higher than those of the control group. The before-and-after comparisons were significant, and the experimental group showed significant improvement in both FEV1 and FVC, two key lung function indicators, after receiving the novel lung function improvement therapy. This not only showed that the therapy was able to significantly improve the patients' lung function in the short term, but also in terms of the long-term trend, the experimental group's lung function level was consistently maintained at a high level, while the control group did not see any significant changes. This result further reinforces the effectiveness and long-term stability of the therapy in improving lung function. Through continuous monitoring and optimization of the treatment regimen, this article is expected to bring benefits to more patients and help them restore and maintain good lung function.

# **4.2 Changes in Blood Biochemical Indicators**

Through the analysis of blood biochemical indexes, this paper found that certain indexes (e.g.

inflammatory factor levels) of patients in the experimental group decreased compared with those in the control group after treatment. This suggests that hanfengji methylin may inhibit the process of pneumoconiosis fibrosis by regulating the inflammatory response.

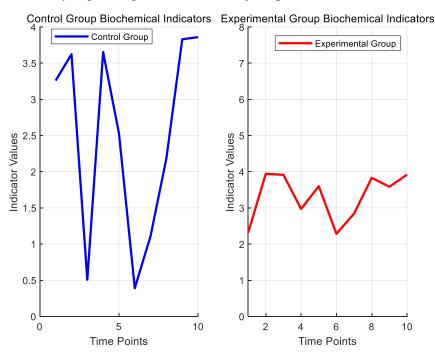


Figure 2: Comparison of blood biochemical markers

When comparing the blood biochemical index data plots of the experimental and control groups (as shown in Figure 2), significant differences can be observed in this paper. The values of the data for the control group fluctuated in the range of 0 to 4 and did not show a significant increase, or decrease over time. This suggests that in the absence of any treatment, or intervention, the blood biochemical parameters of the control group remained at a relatively stable level during the experimental period and did not deteriorate significantly. In contrast, the overall mean value of the data of the experimental group was significantly lower than that of the control group. The values of biochemical indicators in the experimental group fluctuated in the range from 2 to 4, which indicates that this is the ideal level of indicators. By implementing optimisation measures, the blood biochemical indicators of the experimental group were effectively controlled. This comparison further verifies the effectiveness of the new treatment method, indicating that the blood biochemical indicators of the experimental group were significantly improved after receiving the treatment.

# 4.3 Degree of Pulmonary Fibrosis

In the experimental group, the degree of lung fibrosis was reduced compared with the control group in the post-treatment imaging examination. This proved the inhibitory effect of hantahexin methylin on the fibrotic process of pneumoconiosis.

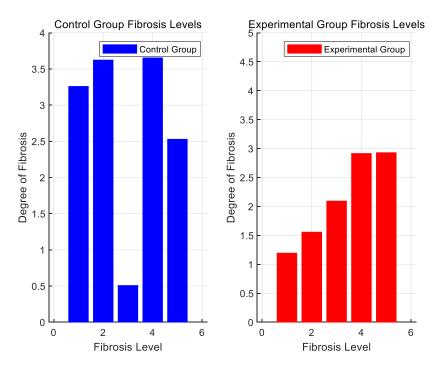


Figure 3: Contrison of the degree of pulmonary fibrosis

For the test of the effect of the new treatment on lung fibrosis, the data in Figure 3 shows how the two groups compared in terms of the degree of fibrosis. The data for the control group fluctuated within a relatively stable fibrosis grade range of 0.5 to 4, which represents a natural improvement in the degree of lung fibrosis that was not observed in the control group during the experimental period in the absence of a specific treatment or intervention. For the experimental group, the data covered the fibrosis grade range of 1.3 to 3, but the distribution pattern of the specific values was different, and its mean value was lower than that of the control group, which indicated that the degree of lung fibrosis in the experimental group was significantly controlled after receiving the new treatment method, and its treatment results were much more effective than those of the control group. Taken together, the values of fibrosis degree in the experimental group showed a lower level compared to the control group. The degree of pulmonary fibrosis in the control group remained stable without treatment, while the experimental group showed a decrease in the degree of fibrosis after receiving the new treatment. This difference was not only reflected in the mean value, but also in the trend of data distribution. This comparative result fully illustrates the positive effect of the new treatment on the degree of pulmonary fibrosis and provides strong evidence for future clinical application.

## 5. Conclusion

Pneumoconiosis is an occupational lung disease caused by long-term inhalation of productive dust, and its main pathological feature is fibrosis of lung tissue. Currently, there is no specific drug for the treatment of pneumoconiosis, and as a drug with anti-inflammatory, antioxidant and antifibrotic effects, the potential therapeutic value of hanpenguijiemethin for pneumoconiosis fibrosis has attracted widespread attention. The aim of this study was to investigate the effect of hanpengi methylin on the process of pneumoconiosis fibrosis by means of a prospective observational study. The study of this paper mainly includes the following parts: firstly, the clinical characteristics of pneumoconiosis patients are described and analyzed; secondly, a prospective

observational study on the treatment of pneumoconiosis fibrosis with hanpenguijiemethicone is designed and implemented; then, the therapeutic effect of hanpenguijiemethicone is evaluated by comparing the lung function and imaging manifestations before and after the treatment; and lastly, the shortcomings of the study are analyzed, and the direction of the future improvement is proposed. In this study, a certain number of pneumoconiosis patients were selected as research subjects and randomly divided into control group and experimental group. The control group received conventional treatment, while the experimental group was treated with hanpengi methylin on the basis of conventional treatment. In the course of treatment, this paper regularly collects the clinical data of the patients, including lung function indexes, imaging manifestations, etc., and records the adverse reactions of the patients. After a certain cycle of treatment, this paper found that the lung function and imaging performance of patients in the experimental group were significantly improved. Specifically, the lung function indexes such as pulmonary ventilation function and diffusion function of the patients in the experimental group were improved, and the degree of pulmonary fibrosis on imaging was also reduced. These results suggest that hanpengi methylin has a certain inhibitory effect on the fibrotic process of pneumoconiosis.

Although this paper has achieved certain results, there are still some shortcomings. Firstly, the sample size of this paper is relatively small, and there may be some chance; secondly, this paper did not explore the mechanism of antifibrotic action of hanfenpropidin, which limits the understanding of the mechanism of action of the drug in this paper; and lastly, this paper did not adequately assess the safety of the drug, which needs to be verified by further studies in the future. In view of the above shortcomings, future studies can be improved in the following aspects. (1) expanding the sample size to improve the reliability and accuracy of the study; (2) conducting in-depth research on the mechanism of the antifibrotic action of hanpaoji meglumine, so as to provide a more adequate theoretical basis for the clinical application of the drug; (3) enhancing the assessment of the drug's safety, so as to ensure that the safety and effectiveness of the drug is ensured in the clinical application. Through these improvements, this paper can provide a more comprehensive understanding of the role and potential of hanpaoji meglumine in the treatment of pneumoconiosis fibrosis and provide more options and possibilities for the treatment of pneumoconiosis.

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