

## Original Article

**Effect of Traditional Chinese Medicine on antituberculosis drug therapy for pulmonary tuberculosis and liver function**Qing Huang<sup>1,2,3,4,5</sup>, Kunxia Li<sup>1,2,3,4,5</sup>, Qian Li<sup>6</sup><sup>1</sup> Wuhan Jinyintan Hospital, Tongji Medical College of Huazhong University of Science and Technology, Wuhan, Hubei PR China<sup>2</sup> Hubei Clinical Research Center for Infectious Disease, Wuhan, Hubei PR China<sup>3</sup> Wuhan Research Center for Communicable Disease Diagnosis and Treatment, Chinese Academy of Medical Science, Wuhan, Hubei PR China<sup>4</sup> Joint Laboratory of Infectious Diseases and Health, Wuhan, Hubei PR China<sup>5</sup> Wuhan Institute of Virology, Wuhan Jinyintan Hospital, Chinese Academy of Sciences, Wuhan, Hubei PR China<sup>6</sup> Wuhan Hospital of Traditional Chinese Medicine, Wuhan, Hubei PR China**Abstract**

**Introduction:** We performed a case-control study to examine the effect of antituberculosis drugs associated with the acupoint application of traditional Chinese medicine (TCM) on pulmonary tuberculosis and the effects on liver function and immune function.

**Methodology:** A retrospective analysis was conducted, dividing hospitalized pulmonary tuberculosis patients into a control group and a study group. The controls were treated with 2HRZE/4HR standard chemotherapy regimen, and the latter was treated with an acupoint application of TCM based on the control group. The clinical efficacy, focus absorption rate, T lymphocyte group level, immunoglobulin level, serum analysis, and liver function index were compared.

**Results:** The study group was absorbed in 32 patients, absorbed in 24 patients, and unchanged in four patients; no one worsened, and the lesion absorption rate was 93.33%. In the control group, 18 patients were remarkably absorbed, 30 were absorbed, 12 were unchanged, and no one deteriorated. The studied group was treated in 12 patients, noticeably resulting in 34 patients, effective in 12 patients, ineffective in 2 patients, and the resultful rate was 96.67%. The effectiveness rate in the control group was 78.33%. According to the blood gas analysis, PA was higher, while IL-6 and PCT were lower in the study group. A lower ALT, AST, and DBIL were observed in the study group ( $p < 0.05$ ).

**Conclusions:** In conclusion, Traditional Chinese Medicine (TCM) acupoint application with antituberculosis medication improves liver and immunological functioning, accelerating recovery and reducing drug-related liver and kidney damage.

**Key words:** Antituberculosis; acupuncture; TCM; pulmonary; liver; immune.

*J Infect Dev Ctries* 2025; 19(4):504-511. doi:10.3855/jidc.18452

(Received 29 April 2023 – Accepted 08 August 2023)

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**Introduction**

Pulmonary tuberculosis is a common clinical infection caused by *Mycobacterium tuberculosis*, primarily affecting the lungs. Clinical investigations have shown an increase in the incidence rate over the past few years. [1]. The difficulty when treating pulmonary tuberculosis is the drug resistance of *M. tuberculosis*. Some researchers have pointed out that autoimmune deficiency exists in patients with retreatment of pulmonary tuberculosis. Additionally, only one drug against *M. tuberculosis* is used to treat patients repeatedly, and the effect is often poor [2]. The number of patients with drug-resistant pulmonary tuberculosis is gradually increasing; drug-resistant pulmonary tuberculosis results from inappropriate and irregular drug use leading to treatment failure. Pneumococcal tuberculosis is a disease that requires

long-term treatment. The treatment effectiveness is poor, leading to a low clinical cure rate and an increase in medical costs to the healthcare system. .

In more and more treatments of recurrent pulmonary tuberculosis, clinicians gradually find that TCM is better recurrent while managing recurrent pulmonary tuberculosis. It is easier for patients to accept it, especially when treating TCM associated with conventional antituberculosis Western medicine, whose therapeutic effect is more obvious. Tuberculosis is an infectious chronic debilitating disease characterized by cough, hemoptysis, hot flashes, night sweats, and gradual weight loss. "Lingshu Jade Edition" mentions, "cough, disfigurement; body heat, weak pulse," highlighting that the symptoms of tuberculosis include emaciation and hot flashes [3]. GE Hong's "Elbow Emergency Prescription" recognized the contagious

nature of tuberculosis, noting that "it can be passed on to others after death, potentially leading to the destruction of entire households." [4]. Waitai pointed out that the patients with tuberculosis could have hot flashes, night sweats, flushing faces, and growing weight loss in the afternoon. If ascites are found, it is a sign of an extremely serious condition. In summary, Traditional Chinese Medicine (TCM) views the pathogenesis of tuberculosis as beginning with the invasion of the pathogen, which initially erodes and damages the lungs. Prolonged internal heat, resulting from yin deficiency and excessive consumption of qi, leads to a further depletion of both qi and yin, and in severe cases, yin deficiency can extend to impair yang. If left untreated, tuberculosis can become chronic and spread to other organs, particularly the spleen and kidneys. In advanced stages, it may result in seminal loss and extreme fatigue [5]. Therefore, the pathological nature of this disease is mainly yin deficiency, which can eventually lead to yin deficiency and exuberant fire, deficiency of both qi and yin, or deficiency of both yin and yang. "Medical Orthodox Laoji" contained "killing insects and alleviating deficiency", which was the guiding principle of the clinical treatment of tuberculosis [6].

TCM has progressed in clinical scientific research, personalized treatments, and adjuvant therapy, which has played a good guiding role when treating drug-resistant pulmonary tuberculosis. The effect of TCM when treating pulmonary tuberculosis is more obvious compared to Western medicine alone. The use of TCM prescription when preventing and treating tuberculosis has the advantage of promoting focus absorption [7]. Acupoint application therapy is the action of TCM on acupoints. The principle is similar to TCM acupuncture, through drugs acting on meridians and then omnidirectional adjustment of the body function of patients and finally play a role in alleviating clinical symptoms and curing diseases [8-10]. The effect of antituberculosis drugs associated with acupoint application of TCM on pulmonary tuberculosis and the effect on liver function and immune function has not been reported.

## Methodology

### *Research design*

A retrospective analysis was conducted, comprising of 120 recurrent pulmonary tuberculosis patients hospitalized from March 2019 to December 2021. They were divided into a control group and a study group according to the treatment plan. The controls were managed with 2HRZE/4HR standard chemotherapy,

and the latter was managed with acupoint application of TCM based on the control group. The controls were 38 females and 22 males, with an average age of ( $43.98 \pm 6.63$ ) years,  $44.67 \sim 72.75$  kg, and a weight of ( $61.54 \pm 5.83$ ). The disease took 2-10 months to progress, with an average of ( $6.52 \pm 3.31$ ) months.

The control group was treated with 2HRZE/4HR standard chemotherapy regimen, H: isoniazid (Tianjin Lisheng Pharmaceutical, H12020232) 0.3 g, once a day; R: rifampicin (Shenyang Hongqi Pharmaceutical, H21021905) weight < 50 kg, 0.45 g, once a day, take on an empty stomach, weight  $\geq 55$  kg, 0.6, once a day, take on an empty stomach; Z: pyrazinamide (Shanghai Xinyi Pharmaceutical, H31020800) 20-30 mg/kg/d, once a day after meals; E: ethambutol (Hangzhou Minsheng Pharmaceutical, H33021602) 15-25 mg/kg/d, once a day after meals. (4 weeks per course of treatment, two consecutive courses of treatment.

In addition to the control group treatment, the study group received acupoint application of TCM. The TCM included *Evodia rutaecarpa* 30 g, *Epimedium* 15 g, *Fuzi* 15 g, *psoralen* 15 g, and *Morinda officinalis* 10 g. All these were mixed, ground into a fine powder, diluted with fresh ginger juice, mixed with raw material medicine mixer, and made into a cylindrical wet medicine cake with a special mold, which was applied to Feishu, Tiantui, Dazhui, renal pelvis, Zhongfu, Qizhong, and other acupoints, and fixed with adhesive tape 2 hours, five times a week. Each treatment course lasted for 4 weeks, with two consecutive treatment courses. Local skin redness and needle-like blisters have occurred in some patients during the application period, which resolved spontaneously after some time. Spicy, irritating, cold, and seafood foods were to be avoided during treatment.

### *History of drinking*

There are 67 patients with a history of drinking and 53 patients without a drinking history. There are 55 patients with a smoking history and 65 patients without.

### *Education level*

Total 30 in elementary and junior high schools, 16 in high schools and technical secondary schools, and 14 in college and above. The study group included 40 male and 20 female participants ranging from 25 to 65 years of age. The average age was  $44.03 \pm 6.48$  years. Their weight was 43.98-72.38 kg with an average weight of ( $61.81 \pm 5.33$ ) kg. The disease took 2-11 months to progress, with an average course of ( $6.83 \pm 2.63$ ) months.

**Inclusion and exclusion criteria**

1) All the selected cases were filed in the first treatment and were positive by sputum tuberculosis test. The diagnosis was made according to the “Diagnostic efficacy Standard of TCM Disease-Pulmonary Tuberculosis diagnosis Standard” issued by the State Administration of TCM; 2) ability to read and write basic material, no cognitive, linguistic or intellectual impairments; 3) no allergy to the drugs used in this study; 4) no immunosuppressant therapy in the past 2 months; 5) high compliance and compatibility of the patients. There was a complete set of clinical data.

The patients who were excluded met the following criteria. The patients who had: 1) the spite of the heart, liver, and kidneys of patients with severe medical conditions; 2) patients with leukopenia caused by hyperthyroidism, hypersplenism, and immune connective tissue diseases; 3) those who refused to participate in the test; 4) those whose skin ulcers or infections were not suitable for acupoint application; 5) those who could not cooperate with treatment because of mental and psychological diseases, were all excluded.

**Observation index**

Clinical efficacy evaluation

The main results were: (1) chest X-ray examination was carried out before and 8 weeks after treatment. The criteria for judging focus absorption in patients with pulmonary tuberculosis were “obvious absorption” (lesion diameter decreased  $\geq 1$ , cavity closure or reduction  $\geq 1$ , stroke incident = 2), “absorption” (lesion diameter reduction  $< 1$  cm, cavity reduction  $< 1$ , stroke incident = 2), “no change” (lesion diameter and cavity did not change remarkably), and “deterioration” (lesion diameter and cavity enlargement or new lesions) [11].

**Absorptivity(%)**

$$= \frac{\text{number of obvious absorption cases} + \text{absorption cases}}{\text{total number of cases}} \times 100$$

(2) after treatment, patients were judged by guidelines for new TCM pharmaceutical clinical research [12], assigned to recovery, remarkable effect, resultful, and ineffective. The improvement rate is less than 30%.

**Overall Response Rate**

$$= \frac{\text{number of cured cases} + \text{noticeably resultful cases} + \text{resultful cases}}{\text{total number of cases}} \times 100$$

Detection of immune function index

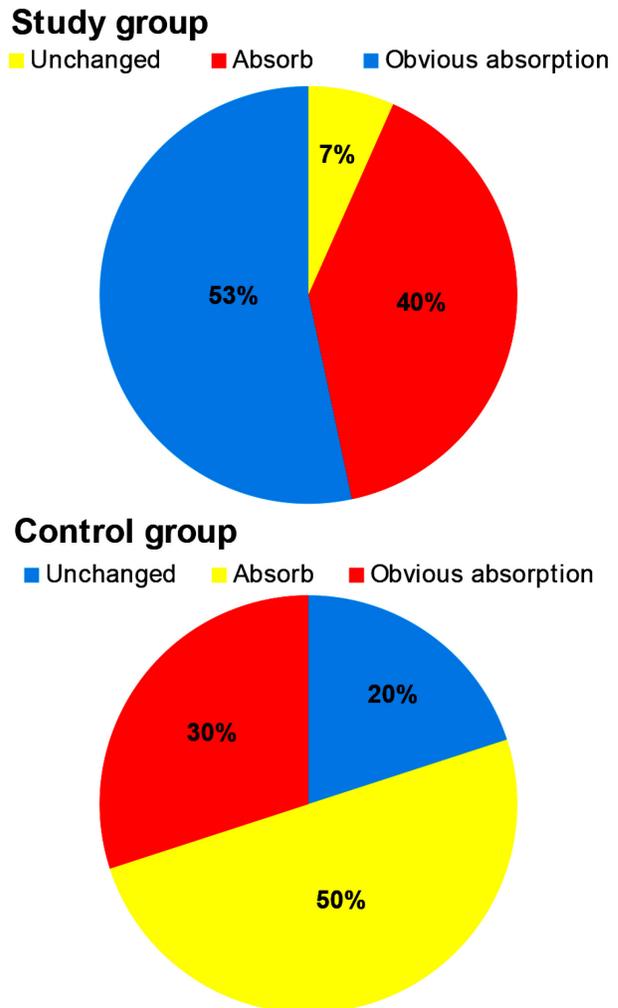
Before and 8 weeks after treatment, the fasting peripheral venous blood 5 ml was harvested and added

to a glass tube containing heparin anticoagulant. Then, the bleeding serum was separated at the speed of 3,000 rpm. The T lymphocyte subsets (CD3<sup>+</sup>, CD4<sup>+</sup>, and CD8<sup>+</sup>) in peripheral blood were detected by flow cytometry. In addition, the levels of serum IgG, IgA and IgM were determined by immune transmission turbidimetry.

Determination of the level of inflammatory factors

Before and 8 weeks after treatment, 5mL venous blood from the upper limbs was taken from all patients on an empty stomach and placed in a glass test tube containing the anticoagulant heparin. The bleeding fluid was separated and put in the refrigerator at -40 °C for detection. Interleukin-6 (IL-6), serum albumin (PA) and serum procalcitonin (PCT) were determined by ELISA.

**Figure 1.** Condition of the lesions in each group.



**Detection of liver function index**

After 8 weeks of treatment, fasting venous blood samples were taken early morning within 8 hours of fasting. Alanine aminotransferase (ALT), aspartate aminotransferase (AST) and direct bilirubin (DBIL) were determined using an i6000 automatic biochemical analyzer (Abbott). Shanghai Haiyan Medical Biology Company provided the reagent and strictly followed the instructions.

**Statistical analysis**

The data were measured by SPSS19.0 software. The measurement data, including liver and immune function indexes, were presented as ( $\bar{x} \pm s$ ) using an independent sample *t*-test. The counting data, such as clinical curative effect and focus absorption rate, were presented as frequency (percentage). The  $\chi^2$  test was adopted and a *p*-value of < 0.05 was considered to be statistically significant.

**Results**

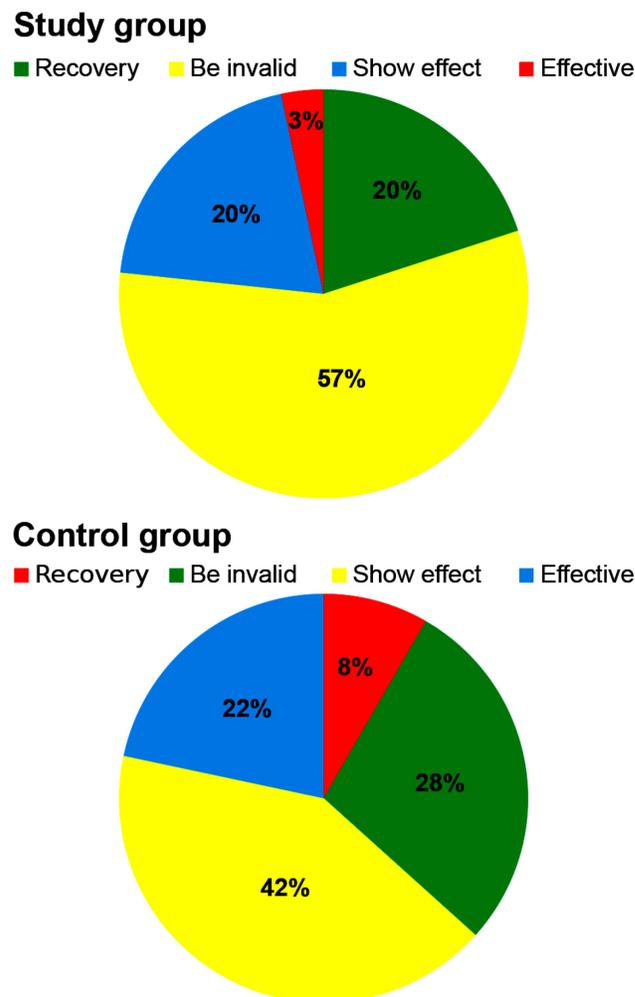
*Comparison of lesions*

In the study group, 32 patients showed remarkable absorption, 24 had partial absorption, and 4 remained unchanged. No patients worsened, with a lesion absorption rate of 93.33%. Eighteen people were remarkably absorbed, 30 people were absorbed, 12 people were unchanged, and no one deteriorated, and the absorption rate of the lesions was 80.00% ( $\chi^2 = 4.615, p = 0.032$ ). Figure 1 shows the details of the distribution of the condition of the lesions.

*Clinical efficacy*

In the study group, 12 people were cured, 34 were noticeably resultful, 12 were resultful, and two were ineffective. The resultful rate of the studied cohort was 96.67%. In the control group, five people were cured, 17 were noticeably resultful, 25 were resultful, and 13 were ineffective. The resultful rate of the controlled cohort was 78.33% (Figure 2). The study group reported a higher treatment success rate ( $\chi^2 = 6.571, p = 0.010$ ).

**Figure 2.** Clinical efficacy in each group.



*T lymphocyte subsets*

A significant increase in peripheral blood levels of lymphocyte subpopulations was observed after treatment compared to before treatment (*p* < 0.05). In comparison with the control group, the CD8<sup>+</sup> level was much lower. Table 1 shows the subpopulation of variants of lymphocytes studied in this research before and after the treatment.

*Comparison of immunoglobulin levels*

There was a remarkable increase in serum IgG, IgA, and IgM levels after treatment in the study group (*p* < 0.05) (Table 2).

**Table 1.** Lymphocyte subpopulations pre- and post- treatments ( $\bar{x} \pm s$ ).

	N	CD3+ (%)		CD4+ (%)		CD8+ (%)		CD4+/CD8+	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
C group	60	68.98 ± 5.23	67.23 ± 6.48	32.72 ± 5.42	34.53 ± 4.62	34.66 ± 3.18	23.68 ± 3.09	0.98 ± 0.41	1.07 ± 0.66
R group	60	69.01 ± 6.14	75.16 ± 6.72	32.45 ± 5.14	39.51 ± 5.66	34.21 ± 3.07	30.58 ± 3.15	0.91 ± 0.39	1.37 ± 0.75
<i>t</i>		0.029	6.580	0.280	5.280	0.628	12.113	0.958	3.326
<i>p</i>		> 0.05	< 0.05	> 0.05	< 0.05	> 0.05	< 0.05	> 0.05	< 0.05

C group: control group; R group: study group.

**Comparison of the level of inflammatory factors**

No remarkable difference was found in IL-6, PA, and PCT in the blood gas analysis before treatment ( $p > 0.05$ ). After treatment, blood gas analysis in the study group was higher, while IL-6 and PCT were lower ( $p < 0.05$ ) (Table 3).

**Comparison of liver function indexes**

No remarkable difference was found in ALT, AST, and DBIL levels before treatment ( $p > 0.05$ ). The levels of liver function indexes were remarkably augmented. The ALT, AST, and DBIL in the study group were higher ( $p < 0.05$ ) (Table 4).

**Discussion**

The basic treatment of pulmonary tuberculosis is mainly chemotherapy, following the principle of “early, combined, appropriate, regular and whole course”. However, drug use is irregular because of drug side effects and a long course of treatment during the treatment period, bringing about the formation of drug-resistant pulmonary tuberculosis, which increases the treatment difficulty and economic burden of patients [13,14]. The resultful treatment of multi-drug resistant pulmonary tuberculosis is the key to tuberculosis and the only way to achieve resultful control of pulmonary tuberculosis [15].

Due to repeated onset, the autoimmune function of patients is destroyed. With the changes in other systems in the body, the clearance effect of antituberculosis drugs on *M. tuberculosis* is greatly reduced. This is the current clinical difficulty when treating pulmonary tuberculosis [16]. The main reason for the retreatment of pulmonary tuberculosis is the destruction of immune function, so antituberculosis drugs are used to treat patients [17]. Since the 1980s, the success rate of ethambutol when treating recurrent tuberculosis has been as high as 80%. However, with the increased frequency and dose, the treatment success rate with ethambutol gradually decreased [18]. Leukopenia caused by antituberculosis drugs will further lead to a decline in immune function and remarkably elevate the disease infection risk [19].

According to the clinical manifestations of pulmonary tuberculosis, TCM classifies it as “fatigue” and “tuberculosis”. The disease is believed to be caused mainly by a pulmonary infection resulting from physical weakness and qi and blood deficiencies. The main clinical manifestations are hemoptysis, cough, hot flashes, etc. The disease will start in the lungs and involve the spleen, stomach, and kidney for a long time. There are many stages of the condition, starting from the deficiency of lung yin, deficiency of both yin and qi, to the deficiency of both spleen and kidney, and finally, the deficiency of both yin and yang. The

**Table 2.** Immunoglobulin levels pre- and post-treatments ( $\bar{x} \pm s$ ) in g/L.

	N	IgA		IgG		IgM	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
C group	60	2.17 ± 0.68	2.23 ± 0.73	12.43 ± 1.42	12.31 ± 1.56	1.45 ± 0.21	1.55 ± 0.26
R group	60	2.14 ± 0.76	2.87 ± 1.35	12.55 ± 1.38	15.63 ± 1.32	1.52 ± 0.34	1.87 ± 0.37
<i>t</i>		0.228	3.230	0.469	12.584	1.357	5.481
<i>p</i>		> 0.05	< 0.05	> 0.05	< 0.05	> 0.05	< 0.05

C group: control group; R group: study group.

**Table 3.** Inflammatory factors pre- and post-treatment ( $\bar{x} \pm s$ ).

	N	IL-6 (pg/mL)		PA (g/L)		PCT (ng/mL)	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
C group	60	123.42 ± 15.42	96.27 ± 6.23	0.14 ± 0.04	0.18 ± 0.02	5.98 ± 4.77	0.56 ± 0.32
R Group	60	122.55 ± 15.46	79.84 ± 5.17	0.13 ± 0.01	0.35 ± 0.06	6.27 ± 5.08	0.17 ± 0.09
<i>t</i>		43.232	15.720	1.879	20.821	0.322	9.088
<i>p</i>		> 0.05	< 0.05	> 0.05	< 0.05	> 0.05	< 0.05

C group: control group; R group: study group; PA: serum albumin; PCT: serum procalcitonin.

**Table 4.** Liver function indexes pre- and post- treatments ( $\bar{x} \pm s$ ).

	N	ALT (U/L)		AST (U/L)		DBIL (μmol/L)	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
C group	60	26.34 ± 5.01	51.25 ± 10.33	27.83 ± 4.31	58.41 ± 13.26	7.27 ± 1.76	42.19 ± 5.75
R group	60	26.29 ± 4.16	43.38 ± 9.16	28.07 ± 4.27	46.54 ± 9.26	7.35 ± 2.21	32.33 ± 6.56
<i>t</i>		0.059	4.415	0.306	5.685	0.219	8.755
<i>p</i>		> 0.05	< 0.05	> 0.05	< 0.05	> 0.05	< 0.05

C group: control group; R group: study group; ALT: alanine aminotransferase (ALT); AST: aspartate aminotransferase; DBIL: direct bilirubin.

treatment approaches should consider unifying the three internal organs of the lung, spleen, and kidney [20]. Acupoint application is to apply TCM to acupoints, exert the effect of medicine through meridian transmission, and then adjust the body function of patients. Compared with traditional oral treatment, it can prevent gastrointestinal reactions to the drugs. It also avoids the loss and change of drug efficacy caused by the lungs, which have the characteristics of strong efficacy and long action time [21]. Some studies have shown that the drug concentration curve entering the patient's body is relatively smooth, and drug concentrations do not peak and valley [22]. Acupoint application on drug concentration can be maintained smoothly for a long time, which has a good effect on increasing patients' immune function and defense system, and then treating patients with recurrent pulmonary tuberculosis [23]. In the study of acupoint application on the body's immune ability, some scholars pointed out that the number of EOS in the observation group remarkably decreased [24]. The cortisol in the body is remarkably augmented, which is conducive to improving non-specific immune function. Compared with the initial patients with pulmonary tuberculosis and recurrent patients with pulmonary tuberculosis, the destruction and erosion of *M. tuberculosis* to the lung tissue are larger in the latter. High-dose and high-frequency chemotherapeutic drug use can impair lung function [25]. The incidence of recurrent pulmonary tuberculosis is closely relevant to immune function. When the immune function is enhanced, the growth and reproduction of *M. tuberculosis* are inhibited. At the same time, the mass reproduction and growth of *M. tuberculosis* in the body means that the body's immune function is reduced.

The immune regulation of pulmonary tuberculosis is mainly mediated by T cells. It has been reported that CD4<sup>+</sup> and CD8<sup>+</sup> T cells attach importance to antituberculosis protective immunity [26]. This study showed that acupoint application associated with conventional antituberculosis chemotherapy drugs could enhance the immune function of cells and tissues in patients. Improving immune function is beneficial to inhibit the reproduction and growth of *M. tuberculosis* in the body. Thus, it attaches importance to when treating recurrent pulmonary tuberculosis. In addition, conventional antituberculosis chemotherapy drugs associated with acupoint application can remarkably enhance the clinical efficacy of recurrent pulmonary tuberculosis patients and promote their focus absorption. The main reason is that *Morinda officinalis*, *Fructus psoralen* and *Herba Epimedii* can all tonify the

kidney and help yang, and psoralen can absorb qi and relieve asthma [27]. Evodia can disperse cold and relieve pain [28], and aconite has the effect of tonifying kidney yang and chasing wind, cold and dampness [29]. The prescription involves tonifying the spleen and kidney and adjusting yin and yang. The selected acupoint Feishu has the effect of tonifying lung qi, mostly used when treating lung deficiency syndrome. Dazhui and Guanyuan have the effect of invigorating yang, tonifying deficiency, and enhancing resistance. As well as strengthening the spleen, Zusanli replenishes qi and strengthens the body. Asthma is the strange acupoint of the back meridian, which is relatively specific to the lungs and has the effect of resolving phlegm and relieving asthma, relieving lung and reducing qi. Tiantui, Luzhong and Zhongfu can widen the chest and regulate qi, relieving cough and asthma. In addition, modern pharmacological studies have also confirmed that acupoint application can be transmitted to the nerve centre through the skin and blood vessels to regulate the immune system and control the disease through neurohumoral regulation.

Studies have shown that in developed countries, 3% to 10% of tuberculosis patients cured with antituberculosis drugs have varying degrees of liver injury. Some patients stop treatment, resulting in the development of the disease and life-threatening [30]. Therefore, more medical staff and patients prefer the safety and advantages of antituberculosis drugs in reducing liver function damage. Our findings suggested that the serum IL-6, PA, and PCT of the patients in the study group were lower after treatment, confirming that the 2HRZE/4HR standard chemotherapy regimen associated with TCM acupoint sticking therapy has a good anti-inflammatory effect. It is mainly because TCM sticking.

## Conclusions

The study concluded that acupoint application associated with conventional antituberculosis therapy could promote the liver function and the humoral and cellular immune function of patients with recurrent pulmonary tuberculosis. Application therapy can enhance the patient's immune function, thereby accelerating the absorption of inflammation and lessening the level of inflammatory factors in the patient's body. Study participants had higher ALT, AST, and DBIL levels, indicating that antituberculosis drugs were associated with TCM acupoint application. It is beneficial to promote the liver metabolic state of patients with retreatment pulmonary tuberculosis and speed up the body's recovery. The main reason is that

the TCM sticking formula used has the effect of regulating yin and yang. TCM acupoint sticking treatment is a physical therapy. The drugs do not directly enter the human body, so the damage to the liver and kidney is small.

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### Conflict of interests

No conflict of interests is declared.

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