Observation on the Curative Effect of Yiyuan Pingchuan Decoction Combined with Ultra-Low Frequency Combined with Physiological Frequency Electrical Stimulation on Chronic Obstructive Pulmonary Disease in Stable Stage

Peng Zhang[1], Qizheng Han[1], YueLi Xu[1], Jifei Geng[2*]

1. Department of Respiratory and Critical Care Medicine, Shandong Second Provincial General Hospital (Shandong ENT Hospital), Jinan 250000, China.

2. Department Emergency, Tai 'an Hospital of Traditional Chinese Medicine, Tai'an 271000, China.

Abstract: **Objective**: To observe the clinical efficacy of Yiyuan Pingchuan Decoction combined with ultra-low frequency combined with physiological frequency electrical stimulation on chronic obstructive pulmonary disease in stable phase. **Method:** 89 patients were randomly divided into control group (44 cases)and observation group (45 cases). The control group was treated with conventional western medicine, while the observation group was treated with ultra-low frequency combined with physiological frequency electrical stimulation and Yiyuan Pingchuan Decoction on the basis of the control group. The 6-minute walking score (6MWT), SGRQ score, Borg fatigue score, lung function, and clinical efficacy after 30 days were observed at day 15 and day 30, respectively. **Results:** The 6MWT, SGRQ score, Borg fatigue score and lung function were improved more significantly in observation group than those in control group ($p<0.05$). The total effective rate of observation group (91.1%) was significantly higher than that of control group (79.5%) ($p<0.05$). **Conclusion:** Yiyuan Pinghuan Decoction combined with ultra-low frequency combined physiological frequency electrical stimulation can significantly improve the 6MWT, SGRQ score, Borg fatigue score and lung function of patients with stable chronic obstructive pulmonary disease, improve clinical efficacy, and then improve the quality of life of patients, so as to improve the clinical prognosis of patients.

Keywords: Yiyuan Pingchuan Decoction; Stable Chronic Obstructive Pulmonary Disease; Upper and Lower Deficiency; Ultra-Low Frequency Combined with Physiological Frequency Electrical Stimulation; Observation of Curative Effect

Introduction

Chronic obstructive pulmonary disease (COPD) is a common preventable and treatable chronic lung disease characterized by persistent airflow restriction and progressive respiratory symptoms [1]. Stable COPD progresses slowly, patients have low immunity, decreased lung function, and the disease has repeated attacks, seriously affecting the quality of life and work [2]. The World Health Organization (WHO) projects that COPD will be one of the top three causes of death worldwide by 2030. The total number of COPD deaths is estimated to increase by 30% in the next 10 years [3]. Therefore, early prevention, discovery and scientific treatment of COPD is an important and arduous medical task in clinical practice. At present, there are many clinical applications of drugs and pulmonary function rehabilitation training for treatment, but there is still a lack of effective treatment for COPD in remission. Extracorporeal diaphragmatic pacemaker therapy is a treatment method that increases the endurance and anti-fatigue ability of the diaphragm by stimulating it with pulse current,

in order to alleviate symptoms in clinical COPD patients. It is increasingly being applied to COPD patients in remission stage [4]. Many reports have proved that traditional Chinese medicine can regulate the occurrence and development of COPD in multiple ways, multiple targets and multiple links, so as to delay the development of COPD, and has great advantages in improving patients' quality of life [5]. Therefore, on the basis of conventional western medicine treatment of COPD, combined with frequency conversion diaphragmatic pacing and Yiyuan Pingchuan Decoction can significantly improve the quality of life.

1. Materials and method

1.1 Diagnostic Criteria

1)The diagnostic criteria of Western medicine are based on the "Guidelines for Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease (Revised 2021 Edition)"[6]. Patients with shortness of breath, cough, sputum and other symptoms are stable or mild, belonging to the stable period;

2)The diagnostic criteria of TCM belong to lung and kidney qi deficiency syndrome according to TCM Diagnosis and Treatment Guide for Chronic Obstructive Pulmonary Disease (2011 Edition) [7].

1.2 Exclusion Criteria

1)Serious heart and lung diseases, acute cardiovascular and cerebrovascular diseases；

2)Uncontrolled type 2 diabetes, autoimmune disease, chronic wasting disease；

3) Other patients unable to complete clinical observation.

1.3 Clinical data

A total of 89 inpatients and outpatients from Shandong Second People's Hospital and Tai 'an Hospital of Traditional Chinese Medicine from June 2019 to June 2021 were selected and divided into two groups according to random number table method. In the observation group, there were 23 males and 22 females, the average age was (62.1±5.1) years, and the average course of disease was (7.3±2.7) years. Moreover, there were 23 males and 21 females in the control group with an average age of (62.2±5.3) years and the average course of disease was (7.1±2.5) years. There was no significant difference in clinical data between the two groups (P>0.05). This study has been approved by the Medical Ethics Committee of our hospital.

1.4 Methods

Patients in control group received conventional Western medicine treatment, mainly inhaling salmeterol ticasone powder (50ug/500ug*60 capsules, produced by Glaxo Operations UK Limited), appropriate nutritional support, oxygen therapy and disease health guidance. Patients in observation group was additionally treated with ultra-low frequency combined physiological frequency electrical stimulation and Yiyuan Pingchuan decoction. The Yiyuan Pingchuan decoction was consisted by Psoralea (15g), walnut (15g), Gecko (Chong) (3g,) platycodon (15g), Houttuynia Cordata (30g), almond (10g), Fructus suzi (15)g, Trichosanthes (15g), which was made into decoction and patients took it in two doses for 20 days.

1.5 Observation indicators

The 6-minute walk test (6MWT), St George's Respiratory questionnaire (SGRQ) score, Borg fatigue score, lung function at 15 days and 30 days and clinical efficacy at 30 days of the two groups were observed. Then the degree of influence on various scores and clinical efficacy changes were observed after treatment in the two groups.

1.5.1 6MWT

6-minute walk distance after treatment.

1.5.2 SGRQ score [8]

SGRQ was used to evaluate the quality of life of patients before and after treatment, including respiratory symptoms, disease impact and activity limitation. Respiratory symptoms: The score was based on the severity of symptoms such as chest tightness (shortness of breath), cough and expectoration. Severe (3 score): Chest tightness (shortness of breath), cough and expectoration were obvious； Mild (1 score): Intermittent chest tightness (shortness of breath), cough, and sputum production were not obvious. A score of 2 was given for symptoms in between. Response score for respiratory symptoms: a decrease of ≥2 points was considered to indicate significant improvement， a decrease of ≥1 point was considered mild improvement and no change in score was considered to be futility. Disease Impact Score: significantly improve—the score decreased by ≥8 points; Slight improvement—a score decrease of ≥4 points was invalid if the score was < 8; Mobility—limitation Score. Invalid: The score decreased by <4 points.

1.5.3 Borg fatigue score

A total of 10 points were scored according to the degree of dyspnea and fatigue: 0—No difficulty breathing or fatigue at all，0.5—very mild difficulty breathing or fatigue, difficult to detect，1—very mild difficulty breathing or fatigue, difficult to detect， 2—Mild dyspnea or fatigue， 3—Moderate dyspnea or fatigue, 4—Mild severe difficulty breathing or fatigue， 5—Severe difficulty breathing or fatigue，6-8—Very severe difficulty breathing or fatigue，9—Very, very severe difficulty breathing or fatigue，10—Extreme difficulty breathing or fatigue, reaching the limit.

1.5.4 clinical efficacy

Excellent: After treatment, pulmonary function tests showed FEV1≥80% predicted value, FEV/FVC≥70%, dyspnea, expectoration, cough and other respiratory symptoms disappeared, and the results of chest X-ray showed that the pulmonary infection disappeared.

Effectivity: After treatment, the predicted value of FEV1 was significantly improved compared with that before treatment, FEV/FVC < 70%, dyspnea, expectoration, cough and other respiratory symptoms disappeared, and chest X-ray results showed that pulmonary infectious lesions partially disappeared.

Invalid: Patients who did not meet the above efficacy criteria.

Total effective rate =(Number of Excellent cases + Number of effective cases)/31×100%

1.6 Statistical analysis

SPSS 21.0 statistical software was used to analyze the data. Measurement data were expressed as mean ± standard deviation ($\overline{X}$ ±s). The differences between two groups or among three groups were compared by t test or $\chi 2$ test. $P < 0.05$meant the difference was significant.

2. Results

2.1 The 6MWT and Brog fatigue score were compared between the two groups before and after treatment

As shown in Table 1, the levels of 6MWT and Brog fatigue score 15 days and 30 days after treatment in the two groups were higher than those before treatment, and the improvement in the observation group was more significant than that in the control group(P＜0.05)

Table 1. The 6MWT and Brog fatigue score were compared between the two groups before and after treatment

Groups	n	time	6MWT (m)	Brog fatigue score
Observation group	45	Before treatment	285.63±65.73	5.43±0.51
		15 days after treatment	331.69±72.73*	4.72±0.56*
		30 days after treatment	383.64±76.16**▲	4.61±0.43**▲
Control group	44	Before treatment	287.31±70.62	5.39±0.48
		15 days after treatment	322.47±71.69	5.12±0.51
		30 days after treatment	347.73±72.37	5.07±0.43

*P<0.05、**P<0.01 VS before treatment；▲P<0.05 VS control group.

2.2 SGRQ scores were compared between the two groups during the treatment

As displayed in Table 2, the SGRQ scores of the two groups after treatment were improved compared with those before treatment, and the improvement in the observation group was more significant (P < 0.05).

Table 2 SGRQ scores were compared between the two groups

Groups	n	time	Respiratory symptom score	Disease impact score	Mobility limitation score
Observation group	45	Before treatment	25.76±4.33	23.46±4.52	14.73±2.31
		15 days after treatment	18.68±3.64*	17.98±3.01*	10.62±1.86*
		30 days after treatment	12.73±2.13**▲	12.36±1.98**▲	6.78±1.39**▲
Control group	44	Before treatment	25.69±4.41	23.54±4.62	14.69±2.28
		15 days after treatment	21.48±4.11	20.17±3.88	12.79±2.11
		30 days after treatment	18.14±3.32	17.36±2.89	9.07±1.44

*P<0.05、**P<0.01 VS before treatment；▲P<0.05 VS control group.

2.3 The improvement of lung function after treatment was compared between the two groups

As shown in Table 3, the lung function levels of the two groups after 15 days and 30 days of treatment were improved compared with those before treatment, and the improvement of the observation group was more obvious cmpared to those in control group (P<0.05).

Table 3 The improvement of lung function after treatment was compared between the two groups

Groups	n	time	FVC(L)	FEV1(L)	FEV1/FVC(%)
Observation group	45	Before treatment	1.92±0.23	1.78±0.27	66.67±8.32
		15 days after treatment	2.28±0.37*	2.21±0.31*	75.45±9.86*
		30 days after treatment	2.57±0.44**▲	2.96±0.38**▲	83.17±11.89**▲
Control group	44	Before treatment	1.94±0.25	1.81±0.28	66.69±8.29
		15 days after treatment	2.15±0.35	1.98±0.28	71.78±8.98
		30 days after treatment	2.32±0.39	2.36±0.33	74.54±9.49

*P<0.05、**P<0.01 VS before treatment；▲P<0.05 VS control group.

2.4 The clinical efficacy was compared between the two groups after treatment

The total effective rate of the observation group was 91.1%, which was significantly higher than 79.5% of the control group(P<0.05,Tbale 4).

Table 4. The clinical efficacy was compared between the two groups after treatment (%)

Groups	n	Effective	Valid	Invalid	Total effective rate
Observation group	45	25(55.6)	16(35.5)	4(8.9)	91.1▲
Control group	44	21(47.7)	14(31.8)	9(20.5)	79.5

▲P<0.05 VS control group.

3. Discussion

Chronic obstructive pulmonary disease (COPD) is a common chronic respiratory disease. The 2017 Global Initiative for COPD pointed out that the main pathological change of the disease is airflow limitation and recurrent respiratory disease. Due to the high fatality rate, this disease easily poses a serious threat to the life safety of patients [9]. Diaphragm is an important source of respiratory power in the body, and the power generated by diaphragm activity can account for more than 3/4 of the total lung ventilation power. However, the diaphragm movement amplitude of COPD patients is reduced and atrophic, and the contractility and fatigue tolerance of the diaphragm are significantly reduced, which further aggravates the patient's condition. At present, the clinical treatment for patients with stable COPD mainly includes drug control, pulmonary function rehabilitation exercise, and long-term home oxygen therapy. Although drug control can relieve the disease and improve the clinical symptoms to a certain extent, organic lesions also gradually aggravate with the recurrence of the disease. Moreover, respiratory function exercise is difficult to achieve long-term stable efficacy due to the limitation of treatment conditions, patient's willpower, compliance and other problems.

At present, physiological frequency electrical stimulation is mostly used in clinical practice, which can improve the ventilation function of patients to a certain extent. However, in recent years, many studies have shown that although physiological frequency electrical stimulation can improve the contractility and fatigue resistance of the diaphragm to a certain extent, the fiber remodeling of the respiratory muscles of patients has not reached the optimal structure. Many studies have shown that ultra-low complex physiological frequency chronic electrical stimulation can improve the diaphragm contractility and anti-fatigue ability in patients with stable COPD compared with physiological frequency electrical stimulation alone [10].

COPD belongs to the categories of "asthma syndrome", "cough", "lung distension" and other diseases in traditional Chinese medicine. Traditional Chinese medicine believes that the pathological changes in the stable stage of COPD are mainly based on the deficiency of the original qi and the deficiency of the internal organs, with kidney deficiency being the most important. Phlegm turbidity, blood stasis, and water consumption are the criteria. The interaction between the deficiency of the original qi and the deficiency of the internal organs promotes the development of the disease [11]. 《Spiritual pivot: The Meridians.》 says: The lung vein of the hand Taiyin,..... Is the movement between the lung distension, inflation and wheezing. It has been pointed out that the pathogenesis of lung distension is the syndrome of mixed deficiency and excess. In the stable stage of COPD, the deficiency of the root and the deficiency of the upper and the deficiency of the lower are the main symptoms, and the deficiency of the kidney is the main symptoms, while phlegm and drink, blood stasis and water and drink are the main symptoms. Researchers considered that the source of qi is in the kidney, and the main is in the lung. The old body function declines, or the kidney is affected by a long illness, the lower element is damaged, the main qi function of the lung is damaged, and the qi machine is reversed, the qi machine of the lung and kidney cannot be integrated and penetrates, resulting in the clear qi is difficult to enter the body, and the turdy qi is difficult to discharge, and stays in the chest. The lung regulates the waterway, the kidney is the main water, and the lung and kidney function are dysfunctional, which leads to the stagnation of water and fluid, thus forming phlegm and drink, phlegm is cloudy for a long time, which is left in the lung, the lung is not smooth, and the qi is also ascribed to the lung, resulting in the lung fullness and cannot collect and fall. Therefore, the disease is marked in the lung, and its origin is in the kidney, which is most closely related to the lung and kidney [12].

Yiyuan Pingchuan Decoction is composed of drugs such as psoraleae, walnut meat, gecko, platycodon grandiflorum, houttuynia cordata, almond, Suzi and Trichosanthis fructus. Among them, psoraleae and walnut meat are the main drugs to invigorate the kidney, absorb qi and relieve asthma, and have the right to gasification. Gecko nourishing essence blood, cough and asthma as the subject medicine, which can enhance the power of warm kidney and Yang, and can absorb qi and asthma. The combination of the monarch and the minister can make up the effect of tonifying the kidney, absorbing qi and relieving asthma. Platycodon grandiflorum, Houttuynia cordata, almond, Trichosanthis fructus and Fructus radix fructus were used as adjuvant drugs to clear heat, benefit lung and dissipate phlegm. Platycodon grandiflorum was also the leading agent of medicine, carrying medicine to the diseased places. All the prescriptions together to fill the kidney, phlegm, asthma effect. Many modern pharmacological studies have confirmed that many components of Yiyuan Pingchuan decoction can improve the respiratory muscle strength of patients, significantly relieve diaphragmatic fatigue, thereby improving lung function and improving the activity tolerance of patients. In addition, Yiyuan Pingchuan decoction can improve the body's immunity, reduce the dosage of western medicine, and reduce the toxic effects of drugs.

In conclusion, Yiyuan Pingchuan decoction combined with ultra-low frequency combined physiological frequency electrical stimulation in the treatment of stable COPD can improve the 6-minute walk test distance, BROG score, Brog fatigue score and other related clinical indicators, relieve related clinical symptoms, so as to improve the quality of life of patients and improve the clinical prognosis. Moreover, the operation of ultra-low frequency combined with physiological frequency electrical stimulation is convenient, and the price of traditional Chinese medicine is relatively low, which is worthy of further clinical application.

References

[1] Chen YK, Feng YK. Interpretation of the key points of GOLD 2017 guideline [J] Modern Medicine Hygiene,2017, 33 (4):481-486.

[2] Shen JY, Shen GZ. Research on traditional Chinese Medicine differentiation and treatment of respiratory failure in acute exacerbation of chronic obstructive pulmonary disease. Chin J Traditional Chinese Medicine, 2018, 36(2):482-484.

[3] Chronic Obstructive Pulmonary Disease Group of Chinese Respiratory Society, Chinese Medical Doctor Association, Chronic Obstructive Pulmonary Disease Working Committee of Chinese Society of Respiratory Physicians. Guidelines for diagnosis and treatment of chronic obstructive pulmonary disease (2021 revision) [J]. Chin J Tuberculosis & Respiratory,2021,44(03):170-205.

[4] Luo LL, et al. Effect of diaphragm pacing on pulmonary function and quality of life in patients with pneumoconiosis complicated with chronic obstructive pulmonary disease [J]. Occupational Health and emergency rescue. 2021,39(02):163-166.

[5] Cao X, Wang Y, Chen Y, et al. Advances in traditional Chinese medicine for the treatment of chronic obstructive pulmonary disease. J Ethnopharmacol. 2023 May 10; 307:116229.

[6] Cheng SL, Lin CH, Chu KA, et al. Update on guidelines for the treatment of COPD in Taiwan using evidence and GRADE system-based recommendations. J Formos Med Assoc. 2021 Oct;120(10):1821-1844.

[7] Zhang BL, Wu MH. Internal Medicine of Traditional Chinese Medicine [M]. 4th Edition. Beijing: China Traditional Chinese Medicine Press, 2017.

[8] Chen J, Feng DC, Tan YY, et al. The efficacy and impact on lung function of Kuanxiong Lifei Tang combined with budesonide in the treatment of stable stage lung qi deficiency syndrome patients with chronic obstructive pulmonary disease [J]. Chinese Journal of Traditional Chinese Medicine. 2021,4.

[9] Ye RH, Zou LL. Clinical observation on the treatment of 100 stable cases of chronic obstructive pulmonary disease in Lingnan region with integrated traditional Chinese and Western medicine [J]. Chinese Journal of Ethnic and Folk Medicine, 2019,28 (12): 102-105.

[10] Cao HL, Liu ZJ, Jiang HY, et al. Observation of the therapeutic effect of ultra-low frequency combined with physiological frequency chronic electrical stimulation on stable COPD [J]. Shandong Pharmaceutical, 2018,58 (40), 57-59.

[11] Li JS, Yu XQ, Traditional Chinese Medicine Staging and Grading Prevention and Treatment Strategies for Chronic Obstructive Pulmonary Disease [J]. Journal of Traditional Chinese Medicine, 2019, 60 (22): 1895-1899.

[12] Zheng J, Huang P, Wu CH. The effect of modified Liuwei Dihuang Tang combined with cardiopulmonary rehabilitation training on serum IL-6, IL-8, Cys-C levels in stable COPD patients [J] Hebei Medical Journal. 2021,27 (05): 767-772.

Fundings: The Science and Technology Development Project of Traditional Chinese Medicine in Shandong Province (No.2020M215).

Corresponding author: Jifei Geng, Department Emergency, Tai 'an Hospital of Traditional Chinese Medicine, Tai'an, 271000, China.