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Effect of rock salt aerosol therapy on quality of life of patients with pneumoconiosis: A multicenter, randomized, double-blind clinical trial

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Abstract: This study aimed to explore the impact of rock salt aerosol therapy on the quality of life in pneumoconiosis patients. It may provide new treatment method for the comprehensive control of pneumoconiosis. A total of 452 subjects from 6 hospitals were divided based on the multi-level hierarchical random design. The patients in the treatment group received conventional comprehensive treatment + rock salt aerosol therapy. The baseline data were collected, including gender, age, age of dust exposure, stage and COPD combination. Cough, expectoration and dyspnea levels were valuated. Both of the two methods exhibited good curative effect following time extension. Rock salt aerosol therapy showed more significant effect compared with routine method. The clinical symptom tends to be stable after two weeks treatment of rock salt aerosol therapy. The curative effect increases with the extension of treatment time. 2-4 weeks for one course of treatment can improve the curative effect. Rock salt aerosol therapy can effectively improve the quality of life of pneumoconiosis patients. It is a good treatment and rehabilitation method for the prevention and treatment of pneumoconiosis, thus is worthy of clinical application.

Keywords: Pneumoconiosis, rock salt aerosol therapy, quality of life.

INTRODUCTION

Pneumoconiosis is one of the most serious occupational diseases that endanger the health of workers. Current data released by the National Health and Family Planning Commission of the People' s Republic of China showed that there were 29,972 cases of occupational diseases in 2014, of which 26,873 cases were pneumoconiosis, accounting for 89.66% (Wang and Li, 2014). Up to 2014, a total of 860,000 cases of occupational diseases were reported in China, of which 777,000 cases were pneumoconiosis, accounting for 90%. Pneumoconiosis mainly occurred in coal mines and washing enterprises, accounting for more than 60%.

The treatment and rehabilitation of pneumoconiosis includes whole lung lavage and comprehensive treatment. Various operations and drugs have more or less side effects. Safe natural healing requires a specific environment to achieve the purpose of disease treatment and rehabilitation. However, there are few reports on such methods in China.

Rock salt aerosol therapy is to simulate the natural cave microclimate for treatment. The patient breathes naturally in a certain amount of rock salt aerosol particles dispersed in the air. The rock salt aerosol particles with diameter at 1 to 5 μm can easily enter the deep respiratory tract and play a therapeutic role (Yu *et al.,* 2017). It plays significant effects on the treatment of asthma, chronic bronchitis, chronic obstructive pulmonary disease and allergic diseases in otolaryngology and dermatology. Its treatment effect in pneumoconiosis is still unclear. This study adopted a multicenter, randomized, double-blind trial to investigate the role of rock salt aerosol therapy in the treatment and rehabilitation of pneumoconiosis.

MATERIALS AND METHODS

This research enrolled 452 cases of pneumoconiosis between November 2016 and April 2017 from six hospitals based on the situation of coal-producing provinces, including China Pingmei Shenma Group Occupational Disease Prevention and Treatment Institute, Sichuan Yibin Chuanmei Group Furong General Hospital, Shaanxi Tongchuan Mine General Hospital, Hunan Occupational Disease Prevention and Treatment Center, Linyi Hotspring Sanatorium of Shandong Province and the Beidaihe Sanatorium of the Chinese Coal Mine Workers (table 1). All patients had signed informed consent and the study was approved by the ethics committee of the six hospitals. The patients were divided based on the multi-level hierarchical random design

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according to the stage, COPD combination and treatment method (table 2). The subjects were assigned to different wards to avoid contamination.

Inclusion and exclusion criteria

Inclusion criteria

The patients were diagnosed based on a reliable history of productive dust exposure, a high-infrared X-ray chest radiograph, combined with occupational hygiene, pneumoconiosis epidemiological survey data, health monitoring data, clinical manifestations and laboratory tests (pneumoconiosis diagnosis criteria: GBZ 70-2015).

Exclusion criteria

The patients existing communicable diseases such as active tuberculosis, acute respiratory infections and cardiac function decompensation heart disease were excluded.

Sample size calculation

According to the sample size estimation formula: $N = [(Z \alpha/2 + Z \beta)\sigma/\delta] 2 (Q1\text{-}1 + Q2\text{ -}1)$, where

$Z\ 0.05/2 = 1.96$, $Z\ \beta=1.282$, $Q1=n1/N$, $Q2=n2/N$, $N= n1 + n2$; σ refers to the population standard deviation, δ refers to the difference between the two population means, $\delta=|\mu1 -\mu2|$. The minimum respiratory distress index δ was used for calculation. $\delta=0.68\text{-}0.62=0.06$ (logarithmic transition), $\sigma=0.08$. The required sample size for each group was approximately 75 cases. The actual sample size in this study was 452 cases, which was greater than the minimum estimate value.

Treatment method

Treatment group

The patients in the treatment group received conventional comprehensive treatment + rock salt aerosol therapy. The conventional comprehensive treatment was same to the control group, and rock salt aerosol treatment program was as follows:

(1) All the subjects received unified dry salt aerosol therapeutic apparatus produced by the AEROMED Company (Russia).
(2) Unified rock salt particle size, dispersion, and aerosol concentration in the salt room.
(3) The treatment time was one hour daily for continuous 4 weeks.
(4) After each treatment, the patient received sample collection and indicator recording before, the second week after and the fourth week after treatment.

The rock salt room construction standards contained the treatment room within $100m^3$. Moreover, The use conditions of rock salt aerosol therapy instrument meet the external environmental climatic factors: Air temperature 10-29°C, relative humidity <60% when the temperature is 25°C and atmospheric pressure 84-106.7 kPa (630-800 mmHg). The main component of rock salt aerosol was NaCL (>97.70%), and the concentration in salt therapy room was 16.88 mg/m^3 (table 3).

The inhalation of NaCL for each treatment was calculated to be 10.12mg at an inspiratory flow rate of 10 L per minute (Davis, Donn *et al*., 2017).

Control group

The patients in the control group received conventional comprehensive treatment according to the routine of each hospital, mainly includes:

(1) Oxygen therapy;
(2) Symptomatic treatment drugs, including anti-inflammatory, cough, sputum, asthma;
(3) Improving pulmonary circulation treatment;
(4) Anti-fibrosis treatment;
(5) Nutrition support treatment;
(6) Chinese medicine treatment.

Data collection

The baseline data were collected, including gender, age, age of dust exposure, stage and COPD combination. The clinical symptom and signs, pulmonary function, blood biochemistry, sputum and adverse reaction of the subjects before treatment, the second week after treatment and the fourth week after treatment were recorded. Cough, expectoration and dyspnea levels were valuated (Yu, Xu *et al*., 2017).

STATISTICAL ANALYSIS

EpiData 3.1 software was used to establish database and data collection. All data analyses were performed on SPSS 20.0 software. The measurement data were presented as mean ± standard deviation. The data were compared by t test, ANOVA, Welch test, LSD-t and Dunnett method. $P<0.05$ was considered as statistical significance.

RESULTS

General characteristics

As shown in table 4 and 5, there was no statistical difference found on gender, age, age of dust exposure, stage, and COPD combination between treatment group and control ($P>0.05$). The adverse reaction rate was 2.6% in the treatment group, including 3 cases of dry mouth, 2 cases of conjunctival congestion and 1 case of blood pressure elevation. No adverse reaction was observed in the control.

Effectiveness evaluation

The cough and sputum scores of the two groups were gradually reduced after treatment with the extension of treatment time, indicating that both treatment methods can improve the symptoms of cough and sputum. However, there was no obvious difference after treated for 4 weeks

Table 1: Subjects sources

Hospital	Cases
China Pingmei Shenma Group Occupational Disease Prevention and Treatment Institute	117
Sichuan Yibin Chuanmei Group Furong General Hospital	102
Shaanxi Tongchuan Mine General Hospital	98
Hunan Occupational Disease Prevention and Treatment Center	59
Linyi Hotspring Sanatorium of Shandong Province	64
Beidaihe Sanatorium of the Chinese Coal Mine Workers	12
Total	452

Table 2: Subjects grouping

Stages	Groups	COPD combination		Total
		With	Without	
I	Treatment group	42	101	143
	Control	43	80	123
II	Treatment group	23	28	51
	Control	28	29	57
III	Treatment group	25	14	39
	Control	25	14	39
Total		186	266	452

Table 3: Aerosol particle size and concentration detection in salt room

Hospital	Grading sampler detection		Dust sampler detection	
	Concentration (mg/m^3)	< 5 μm (%)	Mean concentration	Central concentration
Beidaihe	16.72	81.51	19.00	20.67
Linyi	16.59	70.96	25.84	24.54
Pingdingshan	13.78	72.64	17.33	15.82
Yibin	18.00	60.12	19.57	24.55
Tongchuan	18.62	60.86	28.96	32.44
Hunan	17.58	69.72	18.48	21.24

Table 4: Clinical feature comparison among groups

Gender	Group	Treatment group	Control	Total	χ^2	P value
	Male	233	218	451	1.45	0.49
	Female	0	1	1		
Stage	I	143	123	266	1.41	0.50
	II	51	57	108		
	III	39	39	78		
COPD combination	With	90	96	186	1.27	0.26
	Without	143	123	266		
Stage I with COPD	With	42	101	143	0.95	0.33
	Without	43	80	123		
Stage II with COPD	With	23	28	51		0.70*
	Without	28	29	57		
Stage III with COPD	With	25	14	39		1.00*
	Without	25	14	39		

Table 5: Occupational feature comparison among groups

	Treatment group	Control	t	P value
Age	66.5 ± 12.5	65.8 ± 12.0	0.64	0.52
Age of dust exposure	18.6 ± 11.5	20.2 ± 10.4	1.52	0.13

compared with 2 weeks in both groups, suggesting that cough and sputum tend to stable at 2 weeks after treatment (table 6).

The respiratory dyspnea score in the treatment group gradually decreased with the prolongation of treatment time (P<0.05). However, there was no significant

Table 6: The curative effect on clinical signs comparison between groups

Index	Group	No.	Before treatment	2 weeks after treatment	4 weeks after treatment	df	F	P value	Correct df, G-G method	Correct P value, G-G method
Cough	Treatment	233	1.91±0.51	1.19±0.68*	1.10±0.68*	2	324.63	0.00	1.54	0.00
	Control	219	1.26±1.00	1.13±0.83*	1.05±0.79*	2	11.07	0.00	1.76	0.00
Sputum	Treatment	233	1.87±0.57	1.06±0.54*	1.00±0.56*	2	430.37	0.00	1.606	0.00
	Control	219	0.98±0.84	0.86±0.66*	0.83±0.66*	2	6.41	0.00	1.693	0.00
Dyspnea	Treatment	233	2.77±0.89	2.18±0.79*	2.06±0.78*	2	127.79	0.00	1.91	0.00
	Control	219	2.36±1.04	2.21±0.98	2.29±0.96	2	1.38	0.25	1.91	0.25

Table 7: The quality of life comparison between groups

Group	No.	Before treatment	2 weeks after treatment	4 weeks after treatment	df	F	P value
Treatment	138	59.56 ± 11.08	68.28 ± 9.31*	70.28 ± 10.11*$^{\#}$	2	120.76	0.00
Control	116	57.85 ± 15.12	61.93 ± 14.77	62.95 ± 14.45	2	13.79	0.00

*P<0.05, compared with before treatment; $^{\#}$ P < 0.05, compared with 2 weeks after treatment.

Table 8: Quality of life questionnaire comparison between groups

Index	Group	No.	Before treatment	2 weeks after treatment			4 weeks after treatment		
				Value	Difference value	P value	Value	Difference value	P value
Health condition	Treatment	138	5.73±1.70	6.30±1.48	0.57±1.62	0.16	6.84±1.35	1.11±1.90	0.07
	Control	116	5.58±1.88	5.84±1.85	0.26±1.72		6.24±1.68	0.66±1.99	
Climb small slope	Treatment	138	5.05±2.51	5.52±2.01	0.66±1.90	0.45	5.68±2.76	0.48±2.45	0.46
	Control	116	4.55±2.54	4.76±2.42	0.47±2.24		4.89±2.70	0.21±3.01	
Impact on indoor activities	Treatment	138	6.02±2.18	6.61±2.08	0.59±2.18	0.06	6.84±1.87	0.82±2.29	0.04
	Control	116	6.08±2.40	6.13±2.35	0.05±2.33		6.29±2.44	0.21±2.21	
Impact on outdoor activities	Treatment	138	5.75±2.13	6.43±1.86	0.68±2.24	0.65	6.57±1.82	0.82±2.46	0.14
	Control	116	5.66±2.23	6.21±2.22	0.55±2.24		6.03±2.34	0.37±2.30	
Impact on social activities	Treatment	138	6.23±2.30	6.89±1.90	0.67±2.29	0.04	6.72±2.01	0.49±2.49	0.02
	Control	116	6.26±2.31	6.34±2.32	0.08±2.13		6.03±2.41	0.24±2.19	
Impact on sleep	Treatment	138	7.02±2.11	7.61±1.99	0.59±2.01	0.34	7.34±2.18	0.32±2.23	0.62
	Control	116	6.74±2.21	7.03±2.34	0.29±2.76		6.89±2.22	0.16±2.67	
Feeling bad	Treatment	138	6.75±2.03	7.48±1.57	0.73±2.17	0.02	7.52±1.87	0.77±2.21	0.27
	Control	116	6.82±2.23	6.87±2.37	0.05±2.36		7.26±2.28	0.45±2.34	
Feeling energy than before	Treatment	138	5.59±1.76	6.93±1.94	1.34±2.50	0.00	7.93±1.93	2.34±2.58	0.00
	Control	116	5.42±2.16	5.55±2.12	0.13±2.44		6.53±1.98	1.11±2.44	

difference in the respiratory dyspnea score of the control group before and after treatment, revealing that rock salt aerosol can relieve patients with dyspnea. However, the difference in dyspnea score between the second and fourth weeks was not statistically significant, suggesting that the symptoms of dyspnea tended to be stable at 2 weeks treatment (table 6).

The scores of cough, sputum and dyspnea of the patients at all time points after treatment were significantly higher in the control group than in the treatment group. It indicated that rock salt treatment improved cough, sputum, and dyspnea compared with routine treatment method.

Quality of life assessment

As the quality of life data from three research centers were incomplete, 254 cases of pneumoconiosis patients completed quality of life assessment questionnaires. The quality of life scores after treatment increased significantly in both groups, suggesting that both treatments can improve the quality of life. The difference was statistically significant between 2 weeks and 4 weeks after treatment in the two groups, revealing that prolonging the treatment time can improve the quality of life (table 7). The improvement of quality of life scores at each time point after treatment was greater in the treatment group than in the control group. The scores of the two groups both increased with treatment time extension. The degree of improvement at each time point was greater in the treatment group than in the control group, including activity at home, social activity, bad mood and feelings (table 8). Rock salt aerosol therapy can improve the quality of life of patients with pneumoconiosis, which is significantly better than the conventional control group.

DISCUSSION

Rock salt aerosol therapy, also known as “saline therapy”, is a natural and non-pharmacological medical method that uses natural mineral rock salt to treat respiratory diseases. It is originated in the 19th century and the establishment of a “salt house” through simulating caves in the last 20 years has been used to control and observe the “cave” microenvironment to achieve therapeutic effects. It has become a certain applied in Europe, especially in Russia and other countries to treat respiratory diseases and allergic diseases (Rashleigh, Smith *et al*., 2014). China brought it in 1995 and gradually applied in a few hospitals. Due to the lack of evidence-based medical information, its promotion and application was limited. During rock salt aerosol treatment, the inhaled rock salt particles can be distributed on the airway mucosal surface to adsorb dust, pathogenic microorganisms, heterogeneous protein allergens and other substances that enter the respiratory tract. Meanwhile, the hypertonic effect of rock salt particles can cause bacterial protein dehydration, induce sterilization and bacteriostasis to improve the status of the respiratory tract biological community, and make the airway mucosal edema subsided. Moreover, it may promote the flow of interstitial tissue fluid, change the rheological properties of airway secretions, promote the repair of mucociliary motor function, and make mucus and harmful substances easy to follow the cilia excretion from the body through exercise helps to improve the microcirculation. Rock salt aerosol therapy is a kind of simple operation compared with the potential adverse reactions of drug treatment, the relatively painful process of lung lavage treatment, and the need to take long-term and continuous anti-immunosuppressive agents after lung transplantation. It has a simple treatment process without pain or adverse drug reactions.

The dry salt aerosol therapeutic apparatus grounded and launched dry salt (rock salt) powder with diameter at 1-5 micron, which mixed with air in the "salt house" to form a saturated aerosol state. It was showed that the particles of sodium chloride dry salt aerosol can alter the biological characteristics of *S. pneumoniae* and have an inhibitory effect on its growth and survival. It was reported that the electrophysiological activity of pharyngeal epithelial cells from 10 healthy volunteers was enhanced (Lin, Chen *et al*., 2017). Inhalation of the patient's airway can improve the rheological characteristics of the bronchial contents, promote the clearance of epithelial cilia, and inhibit bacteria, increase the vitality of lung macrophages, and improve the immune function. Salt therapy has significant effects on the treatment of children and adults with asthma, chronic bronchitis, chronic obstructive pulmonary disease, and allergic diseases in otolaryngology and dermatological (Bersenkowitsch, Oncak *et al*., 2018, Feng, Shen *et al*., 2017). Up to now, there is still lack of investigation about the role and related mechanism of rock salt aerosol therapy on pneumoconiosis around the world. In this study, it was found that with the extension of the treatment time, the symptoms of cough and sputum alleviated significantly after treatment, indicating that the treatment was effective in the short term. The symptoms of cough and sputum remained stable in the next two weeks treatment, suggesting that the clinical symptoms of patients with pneumoconiosis tend to be attenuated following prolonged treatment. Our results demonstrated that rock salt aerosol therapy can improve the quality of life of patients with pneumoconiosis. This method is safe and non-toxic. Only a few patients appeared thirsty on the first time treatment and relieved after 2-3 days. It may provide a new method for the pneumoconiosis patients to improve the quality of life.

CONCLUSION

Rock salt aerosol therapy can effectively improve the quality of life of pneumoconiosis patients. It is a good treatment and rehabilitation method for the prevention and treatment of pneumoconiosis, thus is worthy of clinical application.

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