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Special Topic Study

Effect of acupuncture plus medication on the pulmonary ventilation, IFN-γ level and sleep quality in allergic rhinitis patients

针药并用对变应性鼻炎患者肺通气功能、IFN-γ水平及睡眠质量的影响

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Abstract

Objective: To observe the effect of warm-unblocking acupuncture plus fluticasone propionate nasal spray on the pulmonary ventilation, level of interferon-γ (IFN-γ) and sleep quality in patients with allergic rhinitis (AR).

Methods: A total of 112 AR patients were enrolled between January 2013 and August 2018 and were divided into an observation group and a control group by the random number table method, with 56 cases in each group. Patients in the observation group received warm-unblocking acupuncture plus fluticasone propionate nasal spray, and patients in the control group only received fluticasone propionate nasal spray. The nasal symptom score, pulmonary function indexes, the levels of IFN-γ and interleukin (IL)-4 in serum, and sleep quality in the two groups were compared.

Results: After treatment, the total effective rate in the observation group was higher than that in the control group (P<0.05). The nasal symptom score dropped in both groups after treatment (both P<0.05), and the score in the observation group was lower than that in the control group (P<0.05). The pulmonary ventilation indexes all increased significantly after treatment in the observation group (all P<0.05); the forced expiratory volume in 1 second (FEV1) to forced vital capacity (FVC) ratio (FEV1/FVC) and the forced expiratory flow at 50%, 75% and 25%-75% of the vital capacity (FEF50%, FEF75%, FEF25%-75%) increased after treatment in the control group (all P<0.05); the pulmonary ventilation indexes were higher in the observation group than those in the control group (all P<0.05). The level of IFN-γ increased significantly after treatment in the two groups (both P<0.05) and the level of IL-4 dropped significantly (both P<0.05); the observation group had a higher IFN-γ level (P<0.05) and a lower IL-4 level (P<0.05) compared with the control group. Regarding the Pittsburgh sleep quality index (PSQI), the scores of subjective sleep quality, habitual sleep efficiency and sleep disturbances and the general PSQI score decreased significantly after treatment in both groups (all P<0.05), and the scores in the observation group were significantly lower than those in the control group (all P<0.05).

Conclusion: Warm-unblocking acupuncture plus fluticasone propionate nasal spray can effectively control the clinical symptoms and improve pulmonary function in the treatment of AR; this approach can regulate the levels of IFN-γ and IL-4 towards the normal range in AR patients; it can also improve patient's sleep quality. This method can produce more significant efficacy than fluticasone propionate nasal spray used alone.

Keywords: Acupuncture Therapy; Acupuncture Medication Combined; Rhinitis, Allergic; Fluticasone Propionate; Nasal Sprays; Pulmonary Ventilation; Interferons; Sleep

【摘要】目的：观察温通针法联合丙酸氟替卡松鼻喷雾剂对变应性鼻炎(AR)患者肺通气功能、γ-干扰素(IFN-γ)水平及睡眠质量的影响。**方法：**选取2013年1月至2018年8月就诊的112例AR患者，依据随机数字表法分为观察组和对照组，每组56例。观察组患者接受温通针法联合丙酸氟替卡松鼻喷雾剂治疗，对照组患者仅接受与观察组相同的丙酸氟替卡松鼻喷雾剂治疗。比较两组鼻部症状评分、肺功能指标、血清IFN-γ与白细胞介素(IL)-4水平以及睡眠质量情况。**结果：**治疗后，观察组总有效率高于对照组(P＜0.05)；两组鼻部症状评分均低于治疗前(均P＜0.05)，且观察组评分低于对照组(P＜0.05)；观察组肺功能各项指标均较治疗前明显上升(均P＜0.05)，对照组第一秒用力呼气容积占用力肺活量的百分比(FEV1/FVC)、用力呼出50%、75%及25%~75%肺活量的呼气流速占预计值的百分比(FEF50%，FEF75%，FEF25%-75%)较治疗前上升(均P＜0.05)，且观察组肺功能各项指标均明显高于对照组(均

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P＜0.05); 两组IFN-γ水平均较治疗前明显升高(均*P*＜0.05), IL-4水平明显降低(均*P*＜0.05), 且观察组IFN-γ水平高于对照组(*P*＜0.05), IL-4水平低于对照组(*P*＜0.05); 两组匹兹堡睡眠质量指数(PSQI)中睡眠质量评分、睡眠效率评分、睡眠障碍评分及PSQI总分均较治疗前明显降低(均*P*＜0.05), 且观察组各项评分明显低于对照组(均*P*＜0.05)。**结论：**温通针法联合丙酸氟替卡松鼻喷雾剂治疗AR在控制临床症状与改善肺功能方面效果可靠, 可改变患者的IFN-γ和IL-4水平, 使之接近正常范围; 同时可改善患者睡眠, 其效果优于单独使用丙酸氟替卡松鼻喷雾剂。

【关键词】针刺疗法; 针药并用; 鼻炎, 变应性; 丙酸氟替卡松; 喷鼻剂; 肺通气; 干扰素; 睡眠

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Allergic rhinitis (AR) is a kind of non-infectious inflammatory disorder of nasal mucosa manifesting as a group of symptoms such as stuffy and itchy nose, severely affecting the daily life and work of the patients[1]. Fluticasone propionate nasal spray, a commonly used drug for AR, can directly work on nasal mucosa and effectively control the clinical symptoms, but its long-term efficacy is unsatisfactory, let alone it may cause adverse reactions[2]. Traditional Chinese medicine (TCM) can not only produce stable and effective result, but is also safe and easily accepted by patients in treatingeffective for AR[3]. This study adopted warm- unblocking acupuncture plus fluticasone propionate nasal spray to treat AR, aiming to enhance the clinical efficacy and reduce adverse reactions. The report is given as follows.

1 Clinical Materials

1.1 Diagnostic criteria

1.1.1 Diagnostic criteria in Western medicine[4]

Major symptoms: Episodic itchy nose, sneezing, a blocked or runny nose.

Secondary symptoms: Loss of the sense of smell, itchy eyes and throat.

Medical history: Rapid onset, the symptoms can last for a certain period of time (usually for several or a few minutes), no sneezing or stuffy nose during the interval, may be coupled with urticaria and asthma, etc.

Causing factors: Allergens (such as pollen and dust), or environmental changes.

Examinations: Nasal cavity examination may find pale and partially congested mucosa, significant swelling around the turbinate, and discharge during an attack. A nasal smear or allergen skin test may be required when necessary.

1.1.2 Diagnostic criteria in TCM[5]

Conforming to the diagnostic criteria of lung deficiency and contraction of cold: Usually caused by contraction of cold, manifesting as a pale complexion, shortness of breath, coughing, clear phlegm, a thin white tongue coating, and a floating pulse.

1.2 Inclusion criteria

Aligned with the above diagnostic criteria; 20-60 years old; not involved in any systematic treatment for AR within the previous 1 week; informed of the current study and willing to participate in the trial.

1.3 Exclusion criteria

Coupled with severe asthma; pregnant or breast-feeding women; nasosinusitis or vasomotor rhinitis; allergic constitution or allergic to the drug involved in this trial; significant dysfunction of heart, liver or lungs; a previous history of anaphylactic shock or upper respiratory tract infection within 1 month before the onset.

1.4 Statistical analysis

Data analyses were performed using SPSS statistics 21.0. Measurement data that met normal distribution were expressed as mean ± standard deviation ($\bar{x} \pm s$) and *t*-test was used for both between-group and intra-group comparisons. Enumeration data were expressed as percentage and examined by Chi-square test. *P*<0.05 was indicative of statistical significance.

1.5 General data

A total of 112 AR patients visiting the Ear, Nose and Throat (ENT) Department of the Affiliated Hospital of Gansu University of Chinese Medicine between January 2013 and August 2018 were enrolled in the study. The subjects were divided into a control group and an observation group by the random number table method, with 56 cases in each group. There were no dropouts during the study.

The differences in the general data between the two groups were statistically insignificant (all *P*>0.05), indicating the comparability (Table 1).

Table 1. Comparison of the general data

Group	*n*	Gender (case)		Average age ($\bar{x} \pm s$, year)	Average duration ($\bar{x} \pm s$, year)	Type (case)	
		Male	Female			Intermittent	Persistent
Observation	56	30	26	37.3±5.2	6.2±1.1	38	18
Control	56	29	27	37.2±5.3	6.1±1.2	37	19

2 Treatment Methods

2.1 Observation group

2.1.1 Acupuncture treatment

Acupoints: Yintang (GV 29), bilateral Fengchi (GB 20), Yingxiang (LI 20), Feishu (BL 13), Pishu (BL 20), Shousanli (LI 10) and Zusanli (ST 36).

Method: After standard sterilization, Fengchi (GB 20), Shousanli (LI 10) and Zusanli (ST 36) were treated with warm-unblocking acupuncture. Patient was asked to take a sitting position. The doctor pressed the acupoint with his left index finger and punctured the acupoints with the right hand using filiform needles of 0.30 mm in diameter and 25 mm in length. The depth should be within 25 mm. Upon the needling qi arrival, the left hand pressed more intensively while the right thumb twisted the needle handle forward for 9 times. When an obvious tight sensation appeared beneath the needle, heavy-thrusting and light-lifting manipulation was performed for 9 times, followed by forward twisting manipulation for another 9 times. Crossbow-pushing manipulation was then applied to maintain the needling qi for 60 s. The rest acupoints were treated with filiform needles of 0.30 mm in diameter and 40 mm in length. Yintang (GV 29) was punctured superficially till the needle tip reached the root of the nose. Even reinforcing-reducing manipulation was performed upon the arrival of needling qi till the patient felt distending and sour. Yingxiang (LI 20) was punctured with the needle tip towards the wing of the nose by a depth of 10-20 mm, and even reinforcing-reducing manipulation was applied upon the arrival of needling qi till the spontaneous production of tears. The needles for the abovementioned acupoints were removed 30 min later and the acupuncture holes should be pressed at the removal of the needles. Afterwards, the patient changed to a prone position to receive acupuncture at Feishu (BL 13) and Pishu (BL 20). These two points were punctured with the needle tip towards the spine for about 15 mm in depth. Reinforcing manipulation was performed when needling qi was obtained and the needles were not retained. The treatment was conducted once a day for 10 consecutive days.

2.1.2 Nasal spray

Fluticasone propionate nasal spray (FP, GSK, UK) was used, 50 μL for each side each time, once a day for 10 consecutive days. The initial dose should be 2 sprays for each nostril, and the maintenance dose was 1 spray for each nostril when symptoms were under control.

2.2 Control group

Patients in the control group received the same nasal spray treatment in the same way and at the same dose.

3 Observation of Therapeutic Efficacy

3.1 Observation items

3.1.1 Nasal symptom score

Four nasal symptoms, stuffy nose, runny nose, sneezing and itchy nose, were estimated by 0-3 points. The lower the score, the better the condition.

3.1.2 Pulmonary function indexes

Pulmonary function detector was adopted to measure the following parameters: Forced expiratory volume in 1 second (FEV1) to forced vital capacity (FVC) ratio (FEV1/FVC), forced expiratory volume in 1 second percentage of predicted value (FEV1%), percentage of peak expiratory flow to predicted value (PEF%), and forced expiratory flow at 25%, 50%, 75% and 25%-75% of the vital capacity (FEF25%, FEF50%, FEF75%, FEF25%-75%).

3.1.3 Levels of serum interferon-γ (IFN-γ) and interleukin 4 (IL-4)

Peripheral venous blood was drawn once before and after treatment, 5 mL each time. The blood samples were centrifuged at 3 000 r/min for 15 min to separate serum and then kept at −80 ℃ till detection. The serum IFN-γ and IL-4 levels were determined using radioimmunoassay.

3.1.4 Sleep quality

Sleep quality was evaluated by Pittsburgh sleep quality index (PSQI)[6], with subjective sleep quality, habitual sleep efficiency, sleep disturbances and the PSQI general score as the major evaluation indexes. A lower score indicated better sleep quality.

3.2 Criteria of therapeutic efficacy

The criteria of therapeutic efficacy were made according to the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine*[5].

Markedly effective: Symptoms such as stuffy and runny nose were gone, without a relapse during the follow-up, not or only slightly affecting patient's work and life.

Effective: Symptoms such as stuffy and runny nose were notably improved and the number of relapses went down significantly during the follow-up, with certain influence on patient's work and life.

Invalid: Symptoms such as stuffy and runny nose were not improved or even went worse and the relapse during the follow-up was not reduced, significantly affecting patient's work and life.

3.3 Results

3.3.1 Comparison of therapeutic efficacy

There was a significant difference in the total effective rate between the two groups after treatment

(P<0.05), and the efficacy in the observation group was more significant than that in the control group (Table 2).

3.3.2 Comparison of nasal symptom score

There was no significant difference in the nasal symptom score between the two groups before treatment (P>0.05). After intervention, the nasal symptom score declined significantly in both groups (both P<0.05), and the score was lower in the observation group than that in the control group (P<0.05), (Table 3).

Table 2. Comparison of the therapeutic efficacy (case)

Group	n	Markedly effective	Effective	Invalid	Total effective rate (%)
Observation	56	30	24	2	96.4
Control	56	20	23	13	76.8
χ^2-value					9.314
P-value					0.002

Table 3. Comparison of the nasal symptom score ($\bar{x}$ ±s, point)

Group	n	Stuffy nose		Runny nose		Sneezing		Itchy nose	
		BT	AT	BT	AT	BT	AT	BT	AT
Observation	56	2.22±0.21	0.56±0.12[1)]	2.42±0.35	0.57±0.21[1)]	2.24±0.22	0.69±0.17[1)]	2.15±0.22	0.65±0.12[1)]
Control	56	2.19±0.23	1.14±0.16[1)]	2.40±0.37	1.28±0.15[1)]	2.26±0.21	1.19±0.23[1)]	2.17±0.24	1.09±0.17[1)]
t-value		0.721	21.702	0.294	20.588	0.492	13.082	0.460	15.824
P-value		0.473	0.000	0.769	0.000	0.624	0.000	0.647	0.000

Note: BT=Before treatment; AT=After treatment; intra-group comparison, 1) P<0.05

3.3.3 Comparison of pulmonary function indexes

There were no significant differences in the pulmonary function indexes between the two groups before treatment (all P>0.05). After treatment, the pulmonary function indexes all increased significantly in the observation group (all P<0.05), the FEV1/FVC, FEF50%, FEF75% and FEF25%-75% increased significantly after treatment in the control group (all P<0.05), and the indexes in the observation group were markedly higher than those in the control group (all P<0.05), (Table 4 and Table 5).

3.3.4 Comparison of the serum IFN-γ and IL-4 levels

Before intervention, there were no significant differences in the serum IFN-γ and IL-4 levels between the two groups (both P>0.05). After treatment, the level of IFN-γ increased significantly (both P<0.05) and the IL-4 level declined significantly (both P<0.05) in both groups, and the IFN-γ level was notably higher (P<0.05) and the IL-4 level was notably lower (P<0.05) in the observation group than those in the control group (Table 6).

3.3.5 Comparison of sleep quality

There were no significant differences in the subjective sleep quality score, habitual sleep efficiency score, sleep disturbances score and the PSQI general score between the two groups before treatment (all P>0.05). After treatment, the subjective sleep quality score, habitual sleep efficiency score, sleep disturbances score and the PSQI general score all dropped significantly in the two groups (all P<0.05), and the scores in the observation group were significantly lower than those in the control group (all P<0.05), (Table 7).

Table 4. Comparison of FEV1/FVC, FEV1%, PEF% and FEF25% ($\bar{x}$ ±s, %)

Group	n	FEV1/FVC		FEV1%		PEF%		FEF25%	
		BT	AT	BT	AT	BT	AT	BT	AT
Observation	56	74.37±4.68	85.75±5.71[1)]	96.58±11.24	102.75±10.57[1)]	95.76±10.81	103.34±12.58[1)]	96.62±12.67	105.64±16.79[1)]
Control	56	74.39±4.65	78.52±4.93[1)]	96.55±11.27	98.72±10.73	95.79±10.78	98.69±11.63	96.64±12.69	99.68±14.27
t-value		0.023	7.172	0.014	2.002	0.015	2.031	0.008	2.024
P-value		0.982	0.000	0.989	0.048	0.988	0.045	0.993	0.045

Note: BT=Before treatment; AT=After treatment; intra-group comparison, 1) P<0.05

Table 5. Comparison of FEF50%, PEF75% and PEF25%-75% ($\bar{x}$ ±*s*, %)

Group	*n*	FEF50%		FEF75%		FEF25%-75%	
		Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
Observation	56	88.42±16.74	100.85±16.68[1)]	74.58±17.46	93.69±15.72[1)]	78.87±13.47	96.54±15.62[1)]
Control	56	88.40±16.72	94.53±11.46[1)]	75.61±17.44	83.82±16.59[1)]	78.87±13.47	96.54±15.62[1)]
t-value		0.006	2.337	0.312	3.232	0.008	2.830
P-value		0.995	0.021	0.755	0.002	0.994	0.006

Note: Intra-group comparison, 1) $P<0.05$

Table 6. Comparison of the serum IFN-γ and IL-4 levels ($\bar{x}$ ±*s*)

Group	*n*	IFN-γ (ng/L)		IL-4 (pg/L)	
		Before treatment	After treatment	Before treatment	After treatment
Observation	56	7.08±0.88	11.42±2.09[1)]	62.73±13.71	40.17±9.43[1)]
Control	56	7.11±0.91	8.14±0.72[1)]	62.69±13.73	56.22±11.05[1)]
t-value		0.177	11.104	0.015	8.268
P-value		0.860	0.000	0.988	0.000

Note: Intra-group comparison, 1) $P<0.05$

Table 7. Comparison of sleep quality ($\bar{x}$ ±*s*, point)

Group	*n*	Subjective sleep quality		Habitual sleep efficiency		Sleep disturbances		General PSQI score	
		BT	AT	BT	AT	BT	AT	BT	AT
Observation	56	2.17±0.33	1.04±0.17[1)]	2.05±0.25	0.62±0.19[1)]	2.24±0.27	0.79±0.18[1)]	14.44±3.12	5.12±1.03[1)]
Control	56	2.19±0.35	1.57±0.22[1)]	2.03±0.27	1.14±0.23[1)]	2.22±0.29	1.28±0.26[1)]	14.42±3.09	7.71±1.27[1)]
t-value		0.311	14.265	0.407	13.044	0.378	11.596	0.034	11.853
P-value		0.756	0.000	0.685	0.000	0.706	0.000	0.973	0.000

Note: BT=Before treatment; AT=After treatment; intra-group comparison, 1) $P<0.05$

4 Discussion

AR is a refractory recurrent upper respiratory disease. Since it affects breath during sleep, sleep quality may become an issue for AR patients. If not managed well, AR can lead to an increase in the incidence of bronchial asthma and nasosinusitis. Therefore, timely symptomatic treatment is usually suggested in clinic for better control of the disease. Research has found a close association between the onset and development of AR and the immune responses of the body[7]. Under normal condition, T helper cell (Th) 1 and Th2 stay in a relevant balance, which plays a significant role in maintaining the immune balance of the whole body. Th1 produces factors such as IFN-γ and Th2 secrets factors such as IL-4. IFN-γ can encourage the differentiation of Th1 and inhibit the generation of IL-4, thus producing a notable antagonistic effect on immunoglobulin E (IgE). That is why adjusting the levels of IFN-γ and IL-4 can effectively regulate IgE, and then control the attack and development of AR. These two indexes have been used in the diagnosis and predicting the prognosis of AR. Through monitoring the changes in the IFN-γ and IL-4 levels, we can get a clear picture of how the treatment affects the balance between Th1 and Th2. It has been proven that the development of AR may trigger bronchial asthma[8], and the latter will aggravate AR, further damaging the airway and the pulmonary ventilation function. Currently, pulmonary function has been taken as the most commonly used and important test in the diagnosis, differentiation and efficacy evaluation of respiratory diseases. It can thoroughly reflect the airway resistance, the change of which is closely associated with AR.

Fluticasone propionate nasal spray is a nasal steroid hormone, containing fluticasone propionate, which can produce multiple effects including anti-inflammation and anti-virus. This drug can directly act on the nasal mucosa, so that the symptoms such as nasal obstruction and itch can be effectively controlled in a short time. However, its long-term effect is not so satisfactory, and the high recurrence rate is still a concern[9].

AR belongs to the category of Bi Qiu in TCM[10-11]. When the lung qi is weak, the external wind and cold can invade the body through the nose, leading to the

obstruction of lung qi and blood stasis, causing the accumulation of body fluid and the blockage of the nose and causing sneezing, runny nose and other symptoms. In addition, the qi deficiency of the spleen, lung and kidney all can make people susceptible to wind and cold. Therefore, TCM believes that the deficiency of healthy qi (especially lung qi) is the root cause of AR, while wind-cold invasion is the etiological factor[12]. Hence, TCM mainly treats AR with warming and tonifying methods[13].

Warm-unblocking acupuncture is originated from the traditional needling method. It is not only easy-to-operate and takes effect quickly, but also has the advantages of producing marked sensation and significant efficacy. Because its manipulation bears both reinforcing and reducing techniques, it can not only activate meridian qi, but also maintain the needling qi sensation via the crossbow-pushing manipulation. Warm-unblocking needling method can warm meridians and collaterals, promote qi and blood circulation, dispel wind and cold, and strengthen the healthy qi and eliminate the pathogenic factors[14].

This study selected Fengchi (GB 20), the crossing point of the Gallbladder Meridian of Foot Shaoyang and the Yang Linking Vessel, as the major point, and it works prominently in dispelling wind. Yintang (GV 29) is located on the running course of the Governor Vessel. This point was chosen to unblock the meridian qi flow and reinforce yang qi. Yingxiang (LI 20) is known to treat stuffy nose. In this study, it was selected to dredge the nasal cavity, dispel wind and relax the lung. Besides, Feishu (BL 13) and Pishu (BL 20) were used to reinforce the lung and spleen, and consolidate the superficial. Shousanli (LI 10) and Zusanli (ST 36) were selected to warm and unblock qi flow in Yangming Meridians since these points can eliminate wind, unblock collaterals and dredge nasal cavity. Moreover, Zusanli (ST 36) can also reinforce the spleen, the postnatal foundation, to benefit the lung[15-17]. The above acupoints were used together to warm and unblock the meridians and collaterals, activate qi and blood flow, eliminate wind and cold, and reinforce the healthy qi to drive away the pathogenic factors, so as to restore the function of lung in dispersing and descending, and achieve the goal of treatment[18-20].

The study showed that the observation group had a significantly higher total effective rate compared with the control group, denoting that warm-unblocking needling method plus fluticasone propionate nasal spray can produce significant efficacy in treating AR. The nasal symptom score in the observation group was markedly lower than that in the control group after intervention, indicating that this combination treatment can effectively control the AR symptoms such as nasal obstruction and itch. After treatment, the pulmonary function indexes all increased significantly in the observation group, which were also notably higher than those in the control group, suggesting that the combo treatment protocol can improve the pulmonary ventilation function in AR, which may be associated with the down-regulation of nasal inflammatory mediators and the inhibition of inflammatory reactions. The level of IFN-γ was significantly higher and the level of IL-4 was significantly lower in the observation group than those in the control group after treatment, indicating that the combination treatment can better regulate the levels of IFN-γ and IL-4. Compared with the control group, the observation group also achieved better results in the evaluation of the subjective sleep quality, habitual sleep efficiency, sleep disturbances and the PSQI general score, suggesting that the treatment used in the observation group can effectively improve the sleep quality in AR patients.

In summary, warm-unblocking needling method plus fluticasone propionate nasal spray can control the clinical symptoms, improve pulmonary function, balance the levels of IFN-γ and IL-4, and improve the sleep quality in AR. Its treatment efficacy was more significant than using fluticasone propionate nasal spray alone. This study only conducted a short-term observation, and the long-term efficacy observation needs carrying out in future studies.

Conflict of Interest

The authors declared that there was no potential conflict of interest in this article.

Statement of Informed Consent

Informed consent was obtained from the individual participants recruited in this study.

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