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The Latest Development of Sanfu Herbal Patch in the Treatment of Allergic Rhinitis

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Abstract

Allergic rhinitis (AR) is a non-infectious inflammatory disease of the nasal mucosa mainly mediated by IgE after the body is exposed to allergens (Guidelines for diagnosis and treatment of allergic rhinitis, 2010), with paroxysmal episodes of frequent sneezing, a large amount of watery nose, nasal congestion, thickening of the nasal mucosa as the main characteristics (Xuting Ye, Shuili Zheng, & Zhihua Wang, 2016), because it can further induce bronchial asthma, allergic conjunctivitis, otitis media, sinusitis, tracheal and bronchitis, pharyngitis and other diseases, which has a great impact on the quality of life of patients (Chun Wang, Lili Jiang, Zhendong Shi, et al., 2019). Sanfu herbal patch, a method of traditional Chinese medicine winter disease summer treatment, can effectively improve individual immunity and reduce the occurrence of winter diseases. At present, studies have found that the traditional Chinese medicine Sanfu herbal patch as a complementary and alternative treatment of allergic rhinitis has significant effects.

Keywords: Sanfu herbal patch, allergic rhinitis, individual immunity, traditional Chinese medicine, acupoint

1. Introduction

Allergic rhinitis (AR) is defined as a non-infectious inflammatory disease of the nasal mucosa. The mechanism of this disease is due to immunoglobulin E (IgE) mediated mast cell degranulation and mediators release, which can cause a rapid response to allergens, leading to a range of clinical symptoms such as nasal congestion, nasal itching, sneezing, runny nose, etc. (Bernstein, D. I., Schwartz, G., & Bernstein, J. A., (2016). According to epidemiological investigation, the prevalence of AR has increased rapidly in recent years (Greiner, A. N., Hellings, P. W., Rotiroti, G., et al., 2011). It has been calculated that about 10 to 30 per cent of the world's population suffers from the disease. A study of the number of AR patients and the burden of this disease in the Americas, Latin America and Asia Pacific showed that the prevalence was 14% in adults in the United States, 13% in children, about 7% in adults in

Latin America, and about 9% in adults in Asia Pacific (Bernstein, J. A., 2010). AR is known as a chronic disease. Therefore, the quality of life of patients is seriously affected, and the recurrence rate is gradually increasing (Meltzer, E. O., Blaiss, M. S., Naclerio, R. M., et al., 2012). In addition to the original symptoms of AR mentioned above, patients' quality of life is also affected in the following aspects: decreased physical function, social difficulties, sleep disorders, daytime fatigue, lethargy, irritability, depression, and lack of learning and memory (Brozek, J. L., Bousquet, J., Baena-Cagnani, C. E., et al., 2010). At the same time, the economic burden of AR patients is huge, with the total cost of treatment reaching 3.4 billion US dollars per year, and the main components of the cost are prescription drugs and outpatient visits (Meltzer, E. O., 2016). Patients are always easy to ignore the complications of AR, such as headache, allergic conjunctivitis, otitis media, sinusitis, cough, asthma, etc., which have a huge impact on their health (Meltzer, E. O., & Bukstein, D. A., 2011). In addition, the relationship between AR and asthma should be considered (Meltzer, E. O., 2016), because according to this study, 78% of asthma patients suffer from AR, which inspires us that AR may be a high-risk factor for asthma (Casale, T. B., & Dykewicz, M. S., 2004). Considering so many comorbidities, AR patients need to pay more attention to the treatment of pre-existing diseases and the prevention of comorbidities, so that we can reduce the indirect economic input. Today, oral H1 antihistamines and intranasal corticosteroid sprays are widely considered mainstream treatments for AR. These two main classes of drugs block inflammatory pathways to relieve nasal symptoms (Rosenwasser, L. J., 2002; Ridolo, E., Montagni, M., Melli, V., et al., 2014). Intranasal corticosteroids and H1 antihistamines have their own efficacy as first-line treatment. The mechanism of histamine is to inhibit the release of basophil and mast cells, thereby reducing binding to various histamine receptors in glandular, neurogenic and vascular target cells, thereby reducing sensory nerve stimulation and subsequent parasympathetic activity (Platt, M., 2014). However, the disadvantages of this treatment have become apparent (Pampura, A. N., Papadopoulos, N. G., Spičák, V., et al., 2011). As symptoms recur, the effectiveness of the medication diminishes. There is no doubt that the suppression of symptoms also requires more money and more drug doses (Meltzer, E. O., 2016). Therefore, complementary and alternative therapies have become a better choice to treat AR, especially traditional Chinese medicine (Li, X. M., 2009). Studies have shown that SAHP, as one of the complementary and alternative therapies derived from the Qing Dynasty (1636-1912), is also effective in the treatment of AR (Chen, X., Lu, C., Stålsby-Lundborg, C., et al., 2015).

2. Sanfu Herbal Patch

Sanfu herbal patch is called Sanfu acupoint herbal patching (SAHP), which is a method of winter disease summer treatment in traditional Chinese medicine, which improves the individual's immunity through summer treatment, and can effectively prevent and reduce the occurrence of winter diseases, with a wide range of indications (Guiping Liu, and Liping Xu, 2007). According to the *Neijing · Four Qi regulating God* "sage nourishing Yang in spring and summer, nourishing Yin in autumn and winter, from its root" as the theoretical basis, combined with the day moxibustion, applied on the local acupoints with Xin heat diverging medicine, in order to achieve the effect of dispelling cold evil, publicizing meridians and collaterals, tonifying positive Qi (Qiuying Chen, & Kuei Lin, 2016). With the promotion of traditional Chinese medicine, the treatment of Sanfu herbal patch has gradually been accepted and recognized by most people, and has also been applied in various diseases in clinic, such as allergic rhinitis.

2.1 Application Time of Sanfu Herbal Patch

The so-called Sanfu herbal patch, as the name implies, is the need to stick dressings in the dog days. Sanfu is the third heptane day after the summer solstice every year (referring to the Geng day in the Gan Zhi period) as the beginning of the year, the fourth Heptane Day as the middle of the year, and the first heptane day after the beginning of autumn as the end of the year, which is collectively called Sanfu (Feng, S., Han, M., Fan, Y., et al., 2015; Huang, T. P., Liu, P. H., Lien, A. S., et al., 2014; Kung, Y. Y., Chen, Y. C., Hwang, S. J., et al., 2006; Sheng, Y., 2015). The Sanfu period is characterized by the hottest and strongest Yang qi, which is defined as a metaphysical energy with heat in the body to protect the body from diseases (Zhou, F., Yang, D., Lu, J. Y., et al., 2015). In general, the application is applied once in the first 3 days of

the first, middle and last volt every year. 9:00 ~ 17:00 on sunny days is preferable, and it will last for 3 years (Wei Wang, Wenli Zhang, Xiaoyu Chen, et al., 2019). In terms of production, different specifications of 8cm×10cm, 10cm×12cm or 11cm×13cm patches are selected according to the height and body type of patients. In principle, white mustard seed powder (white mustard seed, asarum, Gansui) should be ground for use, ginger juice and white mustard seed powder should be added to make a paste, which should be evenly coated on the non-woven cloth with tongue pressure plate, and the ointment should be covered on the five acupoints of Dazhui, Feishu (Shuang) and Fengmen (shuang). Then non-woven breathable adhesive should be used to fix the ointment, and finally, appropriate amount of white mustard seed powder should be applied on the Tiantu with small medicated paste. In addition, it can also be applied 1 time before 10d and 10d after the last fall to play the role of strong base and solid respectively.

2.2 Clinical Efficacy of Sanfu Herbal Patch

The purpose of SAHP treatment is to make use of the comprehensive effect of herbs absorbed by the skin, acupoint stimulation and time effect, so as to produce good therapeutic effect (Tai, C. J., & Chien, L. Y., 2004). In ancient times, according to the restriction theory of Yin and Yang, in order to warm Yang, drive out cold and balance Yin and Yang in the "dog days" when Yang qi is most prosperous, it can be achieved by supporting Yang Qi at this time (Pengliang Hao, Dandan Jiang, Yuebo Jiang, et al., 2020). The Huangdi Neijing also calculates the flow sequence of the menstrual flow and the opening and closing time of the rise and fall of the human body, which can also achieve the effect by regular acupoint selection according to the "dog days" (Han, B. Y., 2018). According to the Suwen Malaria Theory, "The summer that is obtained here hurts in the summer, and the heat is abundant, hidden in the skin, outside the stomach, and is a place of glory." This is sweaty and untidy. "From the meridian theory, in summer, due to the excessive heat, the human body will dissipate heat by promoting the opening of pores and accelerating blood circulation, and this time can help the external application of drugs quickly reach the affected area and give full play to the pharmacological effect" (Li, W. X., Lou, Y. Q., Pan, H. W., et al., 2014). From the perspective of modern medicine, San Fu patch can enhance the body's immunity by regulating the function of the hypothalamic-pituitary-adrenaline system (Wei, F. L., 1998) and improving the body's immune protein level (Zuo, L., & Meng, K., 2016). It can also regulate the contraction of trachea, bronchus and vascular smooth muscle and gland secretion by stimulating the pulmonary sympathetic and parasympathetic nerves near the acupoints taken for treatment by external application of drugs. Thus, symptoms of respiratory diseases can be effectively alleviated (Pengliang Hao, Dandan Jiang, Yuebo Jiang, et al., 2020).

2.3 Precautions for Sanfu Herbal Patch

Qianlong said in Xiao Qi that "every advantage has its disadvantage, and everything is like this". Similarly, Sanfu herbal patch is no exception. If used improperly, not only no benefit, but also cause harm to the human body. For example, some patients suffer from local redness and large blisters due to poor lifestyle (Chen, X. Y., Zhang, W. L., Wang, W., et al., 2019). Physical factors may also lead to the appearance of bright red spots, allergic swelling, itching and other symptoms in the skin lesions, which seriously affect patients' sleep and lead to mental anxiety (Yan Junli, Li Xiaodong & Chen Yanqing, 2020). Therefore, before application, we should do a good job of health guidance to prevent the occurrence of adverse reactions, such as patients should try to go to the hospital for application, and truthfully inform the personal history, allergy history, family history, physical type, previous application situation, etc. Similarly, the hospital established application files for each application patient, and actively conducted post-treatment care precautions education for patients with first-time application (Yan Junli, Li Xiaodong & Chen Yanqing, 2020). For example, the specific application time varies from person to person, pain and discomfort can be removed in advance, but the application time should not be too long, the skin is prone to blistering, and spicy and stimulating food should be prohibited during application. Abstaining from seafood and other products can greatly reduce the probability of skin allergy (Chen, X. Y., Zhang, W. L., Wang, W., et al., 2019). However, local skin redness, slight itching and burning sensation after application belong to normal drug absorption reaction, so there is no need to worry too much (Tai, C. J., & Chien, L. Y., 2004). Absolutely, doctors should also pay attention to

syndrome differentiation and treatment, and make clear indications for patients (Qiuying Chen, & Kuei Lin, 2016). Only in this way can the effect of Sanfu herbal patch be brought into full play, and its application scope is not limited to cold syndrome (Wen Wei & Huang Liping, 2019).

3. Allergic Rhinitis (AR)

3.1 Pathogenesis of AR

Allergic rhinitis is a complex chronic inflammation of the upper respiratory tract. It belongs to type I allergy. Its pathogenesis is closely related to genetic factors and exposure to environmental allergens. When susceptible individuals are further exposed to allergens, stimulated by cytokines, local CD4+T lymphocytes of nasal mucosa will differentiate into Th2 cells, thus further releasing Th2 cytokines, which will activate vascular endothelial cells to express adhesion molecules such as ICAM-1. The expression of intercellular adhesion molecules can promote the further local migration, adhesion and localization of various lymphocytes to the nasal mucosa (Li, X. Y., Zhang, Y. L., Li, B., et al., 2020). When patients are exposed to allergens, IgE antibodies are produced, which then bind to high-affinity IgE receptors on the surface of mast cells and basophils gathered in the nasal mucosa to sensitize the body (Zhao, X. L., Zheng, X., Xu, H. M., et al., 2021). When the human body comes into contact with the same allergen again, these allergens will combine with IgE antibodies again, and activate effectors through extensive bridging to degranulate mast cells and basophil granulocytes, and finally release histamine, leukotrienes and other bioactive mediators. These mediators will continue to act on some tissues of individuals, which will cause allergic reactions. The resulting series of clinical symptoms (Zhang Yawen & Sun Peili, 2021).

3.2 Clinical Manifestations of Allergic Rhinitis

Allergic rhinitis is characterized by nasal itching, paroxysmal sneezing, a large amount of watery nose, nasal congestion and decreased sense of smell, while bronchial asthma is characterized by episodic cough and wheezing (Erhui Zhang, 2009). Allergic rhinitis often has many non-nasal symptoms: (1) other organs and systemic conditions: headache, thirst, sore throat, posterior rhinorrhea, ear stuffiness, ear itching, poor appetite, fatigue, snoring, sleep respiratory distress and sleep disorders; (2) Psychological state: patients with allergic rhinitis have low self-esteem, depression, trouble, fear, excitement, etc. many times higher than normal people; (3) Often combined with other serious diseases of the respiratory tract, such as asthma, sinusitis, nasal polyps, etc.; (4) The irritation symptoms and itching of the nose itself make it difficult to ensure the quality of life of patients; (5) The use of sedative antihistamine drugs may further affect the quality of life and even cause drivers to cause traffic accidents.

3.3 Treatment Principles of Allergic Rhinitis

The first principle of AR treatment is to avoid contact with allergens, combined with drug treatment: (1) Antihistamines: oral or nasal use of the second generation or new H1 antihistamines is recommended, which can effectively relieve nasal itching, sneezing, runny nose and other symptoms. The course of treatment is usually no less than 2 weeks. It is suitable for mild intermittent and mild persistent allergic rhinitis. (2) Glucocorticoids: nasal glucocorticoids are recommended. Can effectively relieve nasal congestion, runny nose, sneezing and other symptoms. The course of treatment should be no less than 4 weeks for patients with moderate to severe persistence. (3) Anti-leukotriene drugs: effective for allergic rhinitis and asthma. (4) Chromoketones: Eye drops that have a certain effect on relieving nasal symptoms are effective in relieving eye symptoms. (5) Intranasal decongestant: the course of treatment of nasal congestion caused by nasal congestion should be controlled within 7 days. (6) Intranasal anticholinergic drugs: can effectively inhibit runny nose. (7) Chinese medicine: Some Chinese medicine is effective in relieving symptoms (Guidelines for diagnosis and treatment of allergic rhinitis, 2010).

4. Chinese Medicine to Treat Allergic Rhinitis

The treatment of AR by traditional Chinese medicine starts from the whole, according to the symptoms and physical differences of each patient, and gives treatment based on syndrome differentiation, which has achieved obvious clinical effects. The main methods of treating allergic rhinitis with traditional Chinese medicine are internal treatment and external treatment. Among them, the internal treatment of traditional Chinese medicine includes the treatment of zang-fu organs and the treatment of syndrome types. The treatment of zang-fu organs includes the treatment of lung, spleen

and kidney. The treatment can be divided into external wind-cold type, wind heat stagnation lung type, temper weakness type, kidney qi deficiency type, etc. Traditional Chinese medicine external treatment mainly includes nose drops, acupuncture therapy (including needle pricking, acupoint injection, acupoint burying, etc.), moxibustion therapy, acupoint application, scraping and massage therapy, etc. (Di, G. L., Zhu, Z. H. G., Xiong, W., et al., 2022).

Acupoint application refers to applying drugs to specific acupoints to treat diseases, and acupoint application has obvious effect on allergic rhinitis (Wang Yanping, WANG Lai'er & HAO Qiaorong, 2018). In clinical practice, Feishu, Dazhui, Shenshu, Pishu, Fengmen and Yaohuang are usually selected as the main acupoints for prescription formation (Ma Xin, ZHANG Qiongqiong, Xue Xiqing, et al., 2019). In the study on the treatment of AR patients with Chinese herbal acupoint application (Hu, Y., 2020), the drug group was treated with loratadine tablets orally, and the application group was treated with Chinese herbal acupoint application on the basis of the drug group, and the effective rate was 96.08%, higher than the recurrence rate of the drug group, which was 3.92%, lower than the drug group. The results showed that the adjuvant treatment effect of Chinese medicine acupoint application was better, which could reduce the symptoms of rhinitis and reduce the recurrence rate significantly.

5. Sanfu Herbal Patch Involved in the New Development of Allergic Rhinitis

Sanfu herbal patch has obvious therapeutic effect on AR. The therapeutic effects of SAHP are concentrated in three elements: drug penetration and absorption, acupoint stimulation, and time effect (Peng, J., Wu, X., Hu, J., et al., 2012). TCM patches for the treatment of allergic diseases are generally made according to the cold-effect prescription, as recorded in Zhang's Medicine. It consists of four herbs: mustard seed, spicy seed, gansui and fuhuso. Although there are many variations in the prescription of TCM patches for the treatment of AR, these four TCM herbs have been reported to be the most commonly used and dominant ingredients in SAHP clinical trials (Zhou, F., Yan, L. J., Yang, G. Y., et al., 2015). The herbal patch tested by Chen et al. (Chen, X., Lu, C., Stålsby-Lundborg, C., et al., 2015) for the treatment of AR by Sanfu herbal patch also contained these four herbs as main components. Ephedra was chosen as one of the main components. It has been reported in experimental studies to have antiallergic effects by inhibiting the release of allergenic mediators (Gao, Y.-H., & Dang Lina, 2003) and vascular permeability (Ruan Yan, Mitaka Okamoto & Mitsunari Matsuzaki, 2002). The solution has been used to treat AR with GPHCM since the 1980s and has been reported to be effective against AR and asthma (Chen, X., Lu, C., Stålsby-Lundborg, C., et al., 2015). Observational studies on SAHP in patients diagnosed with allergic diseases have shown that SAHP is effective in 60% of AR patients after treatment (Tai, C. J., & Chien, L. Y., 2004; Tai C. J., Chang C. P., Huang C. Y., et al., 2007). However, the patient-reported diagnosis of AR and the uncertain criteria for determining treatment effectiveness limit the interpretation of the results. Preclinical and clinical studies have shown that SAHP promotes the occurrence of AR through immune mechanisms by reducing serum immunoglobulin E (Ig E) (Fang M. S., Dou Y. C., & Yao S. M., 2014). In addition, several randomized controlled trials (RCTS) conducted in mainland China have shown that SAHP has a good effect in the treatment of AR (Chen, X., Lu, C., Stålsby-Lundborg, C., et al., 2015; Mi Jianping & Yu Chaoshen, 2010; Wang N. N., 2013; Liao X. Y., 2008; Liu Yang, 2011; Shi Yingjun, 2011; Zhang J. J., 2012). It has been reported that Sanfu herbal patch mainly on allergic rhinitis sneezing, running and nose itching symptoms have an obvious effect. Results from SF-36 showed significant improvements in GH (general health) and VT (vitality) in patients treated with acupoint herbal patches (Hsu W. H., Ho T. J., Huang C. Y., et al., 2010). Three of these studies found significant improvements in nasal symptoms and quality of life in patients treated with SAHP compared to those treated with placebo (Mi Jianping & Yu Chaoshen, 2010; Wang N. N., 2013). In addition, a randomized controlled trial conducted in Taiwan that evaluated SAHP versus placebo also showed that SAHP was effective, especially for nasal symptoms, and significantly improved patients' quality of life (Hsu W. H., Ho T. J., Huang C. Y., et al., 2010).

As for the immunological mechanism of SAHP in the treatment of AR, although the specific pathogenesis of AR is not clear, the main theory of the immunological pathogenesis is Th1/Th2

imbalance theory. The cytokines produced by Th1 mainly mediate cellular immunity, while the cytokines produced by Th2 mainly mediate humoral immunity. Th1 and Th2 and cells jointly regulate the immune response process of the body through the secreted cytokines. The two inhibit and regulate each other to maintain a dynamic balance and form a complex network system to participate in maintaining the normal function of the body. AR is a pathological immune response triggered by IgE mediated type I allergy, which is characterized by elevated serum IgE levels. T lymphocytes regulate the synthesis of IgE by B lymphocytes. Th1 and Th2 interact with each other in the immune response, with Th1 cytokines down-regulating Th2 cells and vice versa. IFN-γ is the main factor secreted by Th1 cell subsets, which can inhibit the differentiation of Th0 cells into Th2 cells and the synthesis of IgE by B cells. Insufficient IFN-γ can make Th2 cells hyperfunction, cause excessive secretion of IL-4, and lead to significantly increased IgE production. IL-4, a characteristic factor of Th2 cells, is essential to mediate B cell activation and plays a key role in the synthesis and secretion of IgE through the following four ways: (1) promoting the transcription and expression of low-affinity receptor mRNA in cells, leading to the elevation of IgE; (2) Promote B cell secretion and IgG1, and promote the type conversion of IgG to IgE; (3) Increased the expression of CD23 and promoted IgE synthesis; (4) It promotes the expression and presentation of MHC antigens in B cells under the synergistic action of IL-5, IL-6 and IL-13, and promotes the humoral immune response mediated by IgE. The increase of IgE was positively correlated with the increase of IL-4 and the severity of AR. The increase of IL-4 and the decrease of IFN-γ in vivo are the main mechanism of the increase of IgE synthesis in AR patients (Luo Qulan, 2013; Mi Yuqing, Xin Yan, & Li Cunbao, 2005).

6. Summary and Reflection

AR is a completely intractable health problem that affects nearly 1 in 6 Americans, according to published surveys, and generates $2 billion to $5 billion in costs in the global public health system. Federally funded national health surveys, such as NHIS and NHANES, state that it affects 30 to 60 million people in the United States annually, including 10 to 30 percent of adults and 40 percent of children (Seidman M. D., Gurgel R. K., Lin S. Y., et al., 2015). As symptoms get worse, patients can only seek help with medication. However, the adverse reactions of western medicines cannot be ignored (Wallace D. V., Dykewicz M. S., Bernstein D. I., et al., 2008). Frequent use of oral H1 antihistamines and intranasal corticosteroid sprays will undoubtedly make the drug less effective and the dose of the drug will be increased. Therefore, how to treat AR without drug resistance has long puzzled clinicians. So the researchers shifted their focus to complementary and alternative therapies, and found that some of them did reduce the incidence of comorbidities. SAHP is a special Chinese medicine acupoint dressing (Fu, C. W., Shu, Q., Jiao, Y., et al., 2020). The combination of acupoint stimulation and time effect has become a popular treatment for AR. Compared with western medicine, SAHP has the advantages of safety, low cost, no drug resistance and less adverse reactions. According to historical discoveries about ancient China, the first appearance of SAHP originated from Zhang Lu's Treatise on General Practice, written during the Qing Dynasty (1636-1912). He insists that some diseases occur in winter when Yang is weak, so doctors actively use SAHP during the summer, when Yang is strongest. In TCM theory, this is the principle of the so-called "summer treatment of winter diseases" (Wei, C., Zhang, X., Li, P., et al., 2020). Several systematic reviews have demonstrated that SAHP is an effective treatment for chronic diseases, particularly in AR. Based on the meridian theory (Zhou, F., Yan, L. J., Yang, G. Y., et al., 2015; Pang, L., Zhang, H., Lü, X., et al., 2020), modern biologists have discovered that the connection between qi and blood vessels is expressed by meridians, and applying some Chinese herbal medicines to the skin to make it completely absorbed can stimulate the response of the meridians (Wang, G. J., Ayati, M. H. & Zhang, W. B., 2010).

With the gradual promotion of traditional Chinese medicine and increasing attention to personal health, thousands of people are more and more accepting of traditional Chinese medicine treatment, and choose to actively go to medical institutions to receive SAHP treatment in summer to enhance their immunity. Although the systematic evaluation of SAHP's treatment of AR with total effect rate as the main outcome has not been published (Tang, Zhi-feng, Xie, Yu-xian, Xu, Xin-yi, et al., 2019; Huang, Li, He, Yan & Gao, Jiansheng, 2018), more and more clinical studies have shown (Zhou, F., Wu, H. J., Zhai, J. P., et al., 2016) that SAHP is an effective

and safe therapy for the treatment of allergic rhinitis (AR) and actively participates in the disease progression of AR.

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