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Research Article

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Observation on the Efficacy of Nasal Allergen Barrier Agent in the Treatment of Allergic Rhinitis

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Abstract

Objective: *To study the clinical effect of nasal spray allergen barrier agent in children with allergic rhinitis.*

Methods: *Children aged 6-11 years who visited the pediatric outpatient department of Yulin Hospital of Traditional Chinese Medicine in July each year from July 2021 to July 2023 and met the diagnostic criteria for allergic rhinitis were collected. With the consent of their families, 184 children were randomly divided into two groups. The observation group (87 cases) was treated with nasal spray nasal allergen barrier agent; the control group (97 cases) was given oral desloratadine granules 2.5mg once a day. The observation group was additionally treated with nasal spray nasal allergen barrier agent on the basis of the control group, 1 spray per nostril, 4 times a day. The course of treatment lasted for 8 weeks. According to the Visual Analogue Scale (VAS), the changes in the average total scores of sneezing, runny nose and nasal congestion before and after treatment were observed.*

Results: *Before treatment, there was no statistical significance in the average VAS scores of the above three symptoms between the two groups. After 8 weeks of treatment, the total effective rate was 94.3% in the observation group and 80.4% in the control group ($p<0.05$); during the treatment period, the average total score of the observation group was significantly lower than that of the control group ($p<0.05$).*

Conclusion: *The efficacy of nasal spray nasal allergen barrier agent combined with oral desloratadine granules in children with allergic rhinitis is better than that of oral desloratadine granules alone, which provides a reference for further clinical research on organic solute nasal mucosa isolation therapy.*

Keywords: *Allergic rhinitis; Barrier agent; Nasal mucosa isolation.*

Allergic rhinitis is a common disease in pediatrics. Currently, with the advancement of industrialization and the rapid development of cities, its incidence has shown a significant upward trend. At present, 20% of the world's population suffers from allergic diseases, and their prevalence continues to increase [1]. Allergic rhinitis is divided into perennial and seasonal types. Among them, the seasonal type affects the widest population and seriously impacts normal life. This seasonal rhinitis is mostly caused by pollen allergy, also known as pollinosis.

The pathogenesis of seasonal allergic rhinitis is that after inhaling pollen microparticles in the air, they are adsorbed on the surface of the nasal mucosa, stimulating the body to produce and release immunoglobulin E (IgE). After IgE is formed, it is adsorbed on basophils and mast cells in the superficial layer and on the surface of the nasal mucosa, making the body in a sensitized state. When the body comes into contact with the same sensitizing substance again, the substance can combine with IgE to activate enzyme components in basophils, releasing transmitters such as histamine and slow-reacting substances [2]. Blocking allergens from entering the nasal cavity is the best anti-allergic method. The traditional method is local and/or systemic anti-allergic treatment. This method adds a nasal allergen barrier agent to the traditional treatment. It is evenly sprayed into the middle and inferior nasal meatus, forming an isolation layer on the surface of the mucosa, which electrostatically adsorbs allergen particles, thereby reducing the absorption of allergens by the nasal mucosa.

Materials and Methods

The study subjects were 184 children aged 6-11 years who met the diagnostic criteria for allergic rhinitis and visited our department in July 2021 (from July 1 to July 31), and in the same period of 2022 and 2023 (a total of 3 months over 3 years). They had a disease duration of more than 1 year and were clearly diagnosed with seasonal allergic rhinitis. The diagnostic criteria were formulated based on the children's family history, typical allergic history, clinical manifestations, and consistent laboratory test results.

(1) Symptoms: 2 or more of the following symptoms: sneezing, clear nasal discharge, nasal itching, and nasal congestion. The daily symptoms persist or accumulate for more than 1 hour, and may be accompanied by respiratory symptoms (such as cough, wheezing) and ocular symptoms (including eye itching, tearing, red eyes, burning sensation, etc.) and other accompanying disease symptoms.
(2) Signs: Common signs include pale and edematous nasal mucosa, and watery nasal secretions.
(3) Laboratory tests: Allergen testing shows that at least one allergen has a positive skin prick test (SPT) and/or positive serum-specific IgE; nasal secretion testing shows that the proportion of eosinophils under a high-power microscope is > 0.05 (positive) [3].

The 2008 ARIA guidelines propose that mild allergic rhinitis (AR) refers to mild symptoms that have no significant impact on the child's life (including sleep, study, and daily activities); moderate-severe AR refers to symptoms that are troublesome and have an adverse impact on one or more aspects of the child's sleep, study, or daily activities [4]. This study targeted children with moderate-severe AR who started treatment after confirmation. According to the 2020 Japanese AR guidelines [5], it is recommended to evaluate the efficacy of persistent or perennial AR 2-4 weeks after the initial treatment. If symptoms improve, continue consolidation treatment for 4 weeks. Based on these guidelines, our treatment course was designed to be 8 weeks, which is more conducive to observing clinical efficacy.

The subjects were randomly divided into two groups. The control group was given oral desloratadine granules (Hainan Pulisheng Pharmaceutical Co., Ltd.) 2.5 mg once a day. The observation group was given oral desloratadine granules 2.5 mg once a day, and at the same time used nasal spray-type nasal allergen barrier agent Aqi (produced by Wuhan Dazheng Gaoke Biomedical Co., Ltd.), 1 spray per nostril, 4 times a day. The total treatment course was 8 weeks. A total of 184 children completed the 8-week treatment, including 87 in the experimental group and 97 in the control group. There was no statistical significance in the gender ratio.

According to the 2020 American Rhinitis Guidelines [6], which recommend the first evaluation 5-7 days after the initial treatment, we started scoring 1 week after standardized treatment. The evaluation method adopted the Visual Analogue Scale (VAS) for subjective evaluation. Visual scales were distributed to the children's families, including three items: sneezing, runny nose, and nasal congestion. Each symptom was scored from 0 to 10 points from mild to severe. Evaluation started from the second week after treatment. The weekly scoring method was: parents recorded the scores of the above three symptoms once a day, calculated the daily average score of the three symptoms, and calculated the average score of the week at the end of the week. (Marked improvement: ≤1 point; Improvement: 1-6 points; No improvement: ≥6 points). The evaluation lasted for 7 weeks.

Statistical Methods

SPSS 22.0 statistical software was used for data analysis. Measurement data were expressed as mean ± standard deviation (`x±s), and comparison of means between groups was performed using independent-samples t-test. Count data were expressed as rates and analyzed using the chi-square (x^2) test. A P-value < 0.05 was considered statistically significant.

Table 1 shows that after 8 weeks of treatment, the total effective rate in the observation group was significantly higher than that in the control group, with a statistically significant difference (P < 0.05).

Group	Marked improvement	Improvement	No improvement	Total effective rate
Control group （n=97)	43(44.3)	35(36.1)	19(19.6)	78(80.4)
Observation group(n=87)	48(55.2)	34(39.1)	5(5.7)	82(94.3)
x2				7.936
P				0.019

Table 2: The results showed that there was no statistical significance between the two groups of patients before treatment, while the difference in the average score during the treatment cycle was statistically significant (P < 0.05).

Group	Number of cases	Before treatment	Treatment cycle
Control group	97	7.594±1.0237	2.056±1.8
Observation group	87	7.061±1.0849	1.285±1.6
t		0.047	-2.553
P		0.964	0.012

Results

All subjects were randomly divided into two treatment groups, with each treatment lasting 8 weeks. The families of all included children were given a Visual Analogue Scale assessment form, requiring a fixed family member to conduct the assessment once a day. We conducted telephone follow-ups once a week for 8 weeks. The results showed that in the control group, 44.3% of children had significantly relieved allergic rhinitis symptoms, 36.1% had improved symptoms, and 19.6% had no improvement. In the experimental group, 55.2% of children had significantly relieved symptoms, 39.1% had improved symptoms, and 5.7% had no improvement. The difference between the experimental group and the control group was statistically significant (P < 0.01). The adjuvant treatment with the barrier agent showed obvious clinical efficacy in allergic rhinitis. Statistical analysis indicated that applying pollen barrier agent in the nasal cavity on the basis of conventional anti-allergic treatment significantly reduced nasal absorption of pollen, leading to marked alleviation of rhinitis symptoms, which is worthy of widespread clinical promotion.

Discussion

Currently, allergic rhinitis shows a significant increasing trend and has become a global disease with a rapidly rising incidence. Scholars from Italy and other countries reported that a survey covering four continents (Asia, Europe, America, and Africa) [7] showed that the total incidence of allergic rhinitis (AR) is 15%-25%, and reaches over 40% in children and young people.

In terms of treatment, current guidelines recommend nasal spray glucocorticoids as the first choice. However, due to the dynamic effect of the spray and the irritation of aqueous solutions on the nasal cavity, most children are uncooperative. Moreover, most parents believe that hormones may affect their children's physical development, which significantly reduces treatment

compliance. Only a small number of parents can adhere to long-term use of nasal spray hormones. For systemic anti-allergic treatment, it usually takes 1-3 weeks for the drugs to achieve stable therapeutic effects. Clinical observations show that most parents are worried about drug side effects, and even drug resistance after long-term use. Some children experience adverse reactions such as drowsiness and headache. Given the current situation, few families can adhere to long-term medication.

Aqi (the barrier agent) forms a protective film in the nasal cavity based on the electrostatic principle combined with the physiological characteristics of the nasal cavity, which adsorbs allergenic particles and blocks their absorption in the nasal cavity, thereby alleviating symptoms of allergic rhinitis. The nasal mucosa barrier agent is safe to use with few side effects. Through clinical application, we can further study a new type of drug that forms a tight isolation film on the surface of the nasal mucosa after application, which is not easily absorbed, can adsorb allergenic particles, and block the absorption of allergens by the nasal mucosa, thus achieving the anti-allergic purpose

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