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Clinical evaluation of Nasaleze nasal spray on the effect of allergic rhinitis.

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Abstract

Objective: To evaluate the auxiliary efficacy and safety of Nasaleze nasal spray applied to Chinese population with allergic rhinitis.
Methods: 120 patients were selected who were diagnosed with allergic rhinitis, and were randomly divided into two groups: experimental group and control group (the patients in experimental group use Mometasone Furoate Aqueous nasal spray for one spray and Nasaleze nasal spray in the morning and only Nasaleze nasal spray in the evening; the patients in control group respectively Mometasone Furoate Aqueous nasal spray for one spray. The research circle for the two groups is both 2 weeks), and respectively compare the changes in symptoms and sign score of the two groups before and after treatment and the differences between the two groups.
Results: Symptom score and sign score of the two groups are both obviously improved after treatment (P<0.001); the efficacy of experimental group and control group is respectively 86.66% and 90.00%. And there is no obviously difference between the two groups (P>0.05); there is no obviously adverse reactions between the two groups.
Conclusion: When hormonal nasal spray and Nasaleze nasal spray are combined, the efficacy is equivalent to the single hormone. When hormonal nasal spray and Nasaleze nasal spray were simultaneously applied to the patients with allergic rhinitis, they can effectively reduce the use of nasal spray hormone and be with good safety.

Keywords: Nasaleze, Allergic rhinitis, Symptom score, Sign score, Adverse reactions.

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Introduction

Allergic Rhinitis (AR), also called anaphylactic rhinitis, is a common clinical chronic disease. The patients often use nasal spray hormone against control symptoms. However, if they use it for a long time, they will suffer side effects such as nasal cavity dryness and nasal mucosa hemorrhage. It is undoubtedly a gospel to reduce the dosage of nasal spray hormone and do not reduce efficacy simultaneously. Especially, it is more positive and significant for special groups such as children and even pregnant.

Hydroxypropyl methylcellulose nasal spray (trade name: Nasaleze) has appeared in the European market since 1994. It includes a conveying device and hypromellose powder. And when the latter meets water vapor on the mucosa, it forms gel and prevents allergen particles in the air from entering mucous membranes. According to different experimental models for children and adults, the product had a protective effect on allergic reactions [1,2]. Based on the research on adult patient allergic to grass pollen, the product could reduce in the dosage [3]. Even though pollen count is very high, the used dosage should be less than 3 times a day. It has been proved that Nasaleze nasal spray has a good effect on allergic rhinitis. However, there are no related clinical reports for Chinese population. The research aims to further evaluate the auxiliary efficacy and safety of Nasaleze nasal spray applied to Chinese population with allergic rhinitis.

Data and Methods

Research product

Nasaleze nasal spray is with specifications: 500 mg/bottle and production batch No.: MMH134. It is produced by Nasaleze Ltd. It contains hydroxypropyl methyl cellulose. The product in control group is Mometasone Furoate aqueous nasal spray (trade name: Nasonex). It is with specifications: 50 μg × 140 press/bottle and approval No.: H20140100. It is produced by Schering-Plough Labo N.V.

Case selection

All selected patients saw a doctor in our department from July 2014 to October 2014. Inclusion criteria: (1) The patients were male or female of 2 to 60; (2) The patients were diagnosed with allergic rhinitis according to the following aspects [4,5]: 1. Clinical symptoms: More than two symptoms (including two) of sneeze, watery nasal discharge, nasal obstruction, and rhinocnesmus and others occurred, lasted or accumulated more than 1 h each day, and could be with ocular symptoms such as

eye itch and conjunctival congestion; 2. Signs: Pale nasal mucosa, oedema and watery nasal secretion often occurred. They could receive the t nasal endoscope and sinus CT examination according to the circumstances; 3. Skin prick test: To apply standardized allergen reagent, prick the forearm palm skin, and observe results after 20 min. Each test should be based on positive and negative control. Positive control adopted histamine and negative control adopted allergen solvent. The results were judged based on the specification of corresponding allergen reagent. The skin prick test should be carried out at least 7 days after anti-histamine drugs were stopped; 4. Serum specificity IgE detection can be regarded as one of the laboratory indexes to make AR diagnosis. To make a definite AR diagnosis needed the following conditions as the premise: clinical manifestations should be in line with the results of the skin prick test or serum specificity IgE detection; symptom and sign scores should be equal or greater than 6. (3) The patients voluntarily signed a written informed consent letter and agreed to accept verification and data record. (4) The patients had the ability and were willing to comply with the requirements of the research scheme. (5) The patients did not participate in any research on other allergic diseases within 1 week before the research.

Exclusion criteria: (1) the patients with food allergens. (2) Main clinical symptoms: nasal obstruction. It must be studied and judged that the power would reach the nasal cavity; (3) the patients used this product in the past. (4) The patients could not sign the informed consent letter.

Rejection criteria: (1) Researchers thought that the patients could not participate in the research due to a temporary and sudden disease or other events; (2) the patients withdrew the informed consent letter; (3) the patients could not comply with the research scheme.

Methods

Grouping method and entry situation the research belongs to a randomized single blind controlled trial. There are 120 patients who meet the inclusion criteria, are fully informed, obtain informed consent, and agreed to follow therapeutic schedules and accept follow-up. They are randomly divided into two groups: therapeutic group and control group. During the research, the researchers do not tell the patients of the two groups about the difference between the specific therapeutic schedules.

Therapeutic method the THERAPEUTIC GROUP uses Mometasone Furoate nasal spray and hydroxypropyl methylcellulose nasal spray in the morning. And Mometasone Furoate nasal spray is used for the nostrils once (including Mometasone Furoate 50 μg/spray) and then hydroxypropyl methylcellulose nasal spray is used in the morning and there is no interval between them; hydroxypropyl methylcellulose nasal spray is only used in the evening. The control group independently and respectively uses hormone for nostrils once in the morning and evening. The therapeutic cycles are respectively 2 weeks. The research prohibits using therapeutic schedules except for drugs mentioned in the research. However, the research allows using the following drugs: oral antihistamine-loratadine 5 mg-10 mg each time based on needs, and eye drops-sodium citrate. The patients can use the above drugs each day or at intervals according to their own needs and make records.

Therapeutic efficacy evaluation the efficacy is evaluated 2 weeks after all research objects are treated. Specially-assigned person is fixed to be responsible for all scale evaluation and records, inform the patients of further consultation in strict with time, and focus on observing the changes in symptom sign scores.

Scoring standards for symptoms: Sneeze refers to the number of consecutive sneezes per time and rhinorrhoea refers to the number of blowing the nose each day [6]. Specific standards are shown in Table 1.

Table 1. *Scoring criterion of symptoms.*

Grading score	Sneeze (Numbers)	Runny nose (Times)	Nose itching	Stuffy nose
0	<3	NA	NA	NA
1	3~5	≤ 4	Conscious inspiration	Interruption
2	6~10	5~9	Intermittent or interactive	Endurable formication
3	≥ 11	≥ 10	Mouth breathing almost all day	Unbearable formication

Scoring standards for signs: Inferior turbinate is close to nasal base and nasal septum. And concha nasalis media or its sticky polypoid change and formation are invisible. The sign gets 3 scores; Inferior turbinate is close to nasal septum (nasal base). There is small gap between inferior turbinate and nasal base (nasal septum). The sign gets 2 scores; Turbinate is slightly swelling. And nasal septum and concha nasalis media are visible. The sign is 1 score; Turbinate is not swelling. And nasal septum and concha nasalis media are visible. The sign is zero score.

Efficacy calculation: Efficacy is evaluated according to symptom and sign scores through the formula: Efficacy (%)=(total score before treatment-total score after treatment) / total score before treatment × 100%.

When efficacy is equal and greater than 66%, it is excellent; when efficacy varies from 65%~26%, it is effective; when efficacy is less than or equal to 25%, it is invalid. It represents the proportion that the number of the patients with excellent efficacy, effective efficacy and no efficacy accounts for. Excellent efficacy rate plus effective rate is total effective rate.

Minor variables: Oral drug situation of the patients of the two groups during the treatment should be recorded. The use of loratadine 5 mg is equal to 5 scores. The changes in oral drug score of the patients of the two groups should be compared.

Adverse reactions and follow-up

To ask if the patients suffer adverse reaction in follow-up 2 weeks after ending treatment, confirm or exclude local and systematic adverse symptoms. To tell the patients that they have the right to contact researchers and consult any questions at any time in emergency situations and hint that adverse effects of scheme breach or difficulty in participation should be immediately reported to researchers.

Statistics

Data was calculated with SPS20.0 statistical software, represented with mean ± SD according to t test, and adopt χ^2 to test count data. P<0.05 represents difference with statistical significance.

Table 2. *The scores of two groups before and after treatment (Mean ± SD).*

Group	n	Pre-treatment	Post-treatment	t	p
Treatment	60	8.70 ± 2.51	4.6 ± 1.27	7.49	<0.01
Control	60	9.03 ± 2.10	4.7 ± 1.21	8.17	<0.01

Table 3. *Comparison of total curative effect between two groups (cases).*

Group	n	EXC*		EFF*		INE*		TER*
		n	%	n	%	n	%	%
Treatment	60	37	61.66	15	25.00	8	13.33	86.66
Control	60	41	68.33	13	21.66	6	10.00	90.00

*EXC: Excellent; EFF: Effective; INE: Ineffective; TER: Total Effect Ratio.

Results

There are 120 selected patients who meet with the requirements of experimental scheme in total. Among them, 60 patients are distributed in the experimental group and 60 patients are distributed in the control group. All patients receive the experiment and follow-up. Among them, in the experimental group, 34 male patients and 26 male patients of 39.90 ± 12.85 are with the course of disease of 4.97 ± 4.40; in the control group, 32 male patients and 28 female patients of 37.05 ± 11.51 are with the course of disease of 4.40 ± 2.79; symptom and sign scores are 8.70 ± 2.51 in the treatment group and 9.03 ± 2.10 in the control group. The baselines of the two groups are obviously different and have comparability. During the treatment, oral drug scores in the therapeutic group and the control group are respectively 6.35 ± 2.28 and 6.21 ± 2.49. There are no obviously differences between the two groups, which do not affect the evaluation of therapeutic efficacy. Symptom and sign scores of the two groups are obviously improved (P<0.01) (Table 2) after treatment compared with those before treatment; the effective rate of the control group and the experimental group is respectively 86.66% and 90%. There is no difference between the two groups (P>0.05) (Table 3); There are no obviously adverse reactions in the two groups.

Discussion

Allergic rhinitis is a common clinical disease and gradually increases in the global incidence [7]. At present, there are various drugs that can be applied to treat allergic rhinitis. Glucocorticoid nasal spray has the advantages of simple operation and convenient application and is one of drugs that can effectively and rapidly control the clinical symptoms of the patients [8]. However, long-term use perhaps causes local side effects. In addition, the evidences that ensure special population such as too young children and pregnant women are scarce, so that it is very meaningful to seek a drug that is safe and effective and can partly replace external hormones [9,10]. Hydroxypropyl methyl cellulose is a medical polymer material with stable physical property. It can be used together with antihistamine and glucocorticoid spray due to its physical mechanism [11,12]. It has been verified based on the experience of countries and regions in Europe that hydroxypropyl methyl cellulose nasal spray can reduce the dosage of local hormone for patients with allergic rhinitis [13]. In addition, when it is used together with other drugs, it will not diminish the clinical pharmacological effect of other drugs and cause any adverse reactions [14].

In order to observe the auxiliary efficacy and safety of the nasal spray applied in yellow population (China) with allergic rhinitis, we made the above-mentioned research. According to research results, when hormonal nasal spray drug with 1/2 times quality and Nasaleze nasal spray are used together, the efficacy is equal to that of single hormonal nasal spray drugs and there is no obviously adverse reactions. If the nasal spray is applied to the patients with allergic rhinitis, it can effectively reduce the application amount of nasal spray hormone. In addition, special population such as children and pregnant women are not restricted. It is worthy to be popularized in clinical application. However, our research samples are limited, so we need to make further observation and verification through bigger sample data in the future.

References

1. Aivazis V, Bourli E, Maratou E. Study of mucociliary clearance and peak nasal inspiratory flow rate in children before and after therapy with natural cellulose powder. Nea Pediatrica Chronica 2005; 5.

2. Emberlin JC, Lewis RA. A double blind, placebo-controlled cross over trial of cellulose powder by nasal provocation with Der p1 and Der f1. Curr Med Res Opin 2007; 23: 2423-2431.
3. Emberlin JC, Lewis RA. A double blind, placebo controlled trial of inert cellulose powder for the relief of symptoms of hay fever in adults. Curr Med Res Opin 2006; 22: 275-285.
4. Bousquet J, Khaltaev N, Cruz AA, Denburg J, Fokkens WJ. Allergic Rhinitis and its Impact on Asthma (ARIA) 2008 update (in collaboration with the World Health Organization, GA(2)LEN and AllerGen). Allergy 2008; 63: 8-160.
5. Bousquet J, Van Cauwenberge P, Khaltaev N; Aria Workshop Group; World Health Organization. Allergic rhinitis and its impact on asthma. J Allergy Clin Immunol 2001; 108: S147-334.
6. Wandalsen GF, Miranda C, Ensina LF, Sano F, Amazonas RB. Association between desloratadine and prednisolone in the treatment of children with acute symptoms of allergic rhinitis: a double-blind, randomized and controlled clinical trial. Braz J Otorhinolaryngol 2016.
7. Đuric-Filipovic I, Caminati M, Kostic G. Allergen specific sublingual immunotherapy in children with asthma and allergic rhinitis. World J Pediatr 2016; 12: 283-290.
8. Miller S, Bromley RL, Pleiss MA. Compositions and methods for induction of antigen-specific tolerance 2016.
9. Magyar P, Herjavecz I, Hirschberg A. Effectiveness and tolerability of the glucocorticoid mometasone furoate given as nasal spray in seasonal allergic rhinitis. Orvosi Hetilap 2000; 141: 1407-1411.
10. Fujimura M, Ishimaru H. Corrigendum to influence of a diester glucocorticoid spray on the cortisol level and the CCR4+ CD4+ lymphocytes in dogs with atopic dermatitis: open study. J Veter Med 2016; 2014: 394-419.
11. Amaral EB, Covesi LK, Rego PB. Pharmaceutical composition comprising desloratadine and prednisolone and their use: US20150306111, 2015.
12. Hargreaves KM, Bruno JG. Compositions of matter that reduce pain, shock, and inflammation by blocking linoleic acid metabolites and uses 2015.
13. Poletti D. Nasal inflammation and its response to local glucocorticoid regular treatment in patients with persistent non-allergic rhinitis: a pilot study. J Inflamm 2016; 13.
14. Mener DJ, Shargorodsky J, Varadhan R. Topical intranasal corticosteroids and growth velocity in children: a meta-analysis. Int Forum Allergy Rhinol 2015: 95-103.

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