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Comparison of the Efficacy of Different Doses of Glucocorticoid Nasal Spray Combined with Loratadine in the Treatment of Rhinitis in Children: A Randomized Clinical Trial

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ABSTRACT

Pediatric rhinitis is a common recurrent disorder that may progress to asthma or sinusitis in severe cases. This study aimed to compare the efficacy of different doses of glucocorticoid nasal spray combined with loratadine for rhinitis in children, and provide evidence for optimizing clinical treatment.

A total of 150 children with rhinitis admitted from June 2022 to June 2024 were divided into three groups: group I (low-dose group, n=50), group II (medium-dose group, n=50), and group III (high-dose group, n=50). Patients in all three groups were treated with a glucocorticoid nasal spray with loratadine combined with antihistamines. The immune function, serum inflammatory factor level, quantitative Lund-Kennedy score by nasal endoscopy, nasal symptom score, Quality of Life Questionnaire (RQLQ) scores, clinical efficacy, incidence of adverse events, and treatment compliance were assessed.

Post-treatment, all indices improved in the three groups. The percentages of $CD4^+$ and $CD8^+$ T cells, IL-10 content, and clinical efficacy in groups II and III were significantly higher than those in group I, while the immunoglobulin E (IgE), IL-6 and IL-17 content, the quantitative Lund-Kennedy score of nasal endoscopy, the children's nasal symptom scores, the RQLQ scores, and the incidence rate of adverse events were below in group I. No significant differences were found between groups II and III in all indices, nor in treatment compliance across the three groups.

Loratadine combined with a glucocorticoid nasal spray therapy effectively improves clinical outcomes, inflammation, immune function, symptoms, and quality of life in rhinitis in children, with high clinical application value.

Keywords: Child; Glucocorticoid nasal sprays; Inflammation; Loratadine; Rhinitis

INTRODUCTION

Allergic rhinitis (AR) is an allergic inflammatory condition of the nasal mucosa mediated by immunoglobulin E (IgE) in atopic individuals following allergen exposures. And it is considered one of the global

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intractable diseases. The disease presents with perennial or seasonal episodes, and its clinical manifestations are mainly sneezing, running nostrils, itchy nostrils, blocked nostrils, and olfactory dysfunction.[1] The prevalence of AR is increasing worldwide due to social progress, industrialization, and changes in the social environment, and epidemiological studies of AR conducted in several countries have reported a prevalence of AR ranging from 3% to 19%, with the global prevalence increasing from the initial 4% to 30% today, most commonly in children and adolescents.[2]

Childhood AR is a common chronic non-infectious disease of the respiratory tract in children, with nasal congestion, itchy nose, sneezing, and profuse, clear watery nasal discharge as the main clinical manifestations. Due to the special anatomical structure of children's respiratory tract compared with that of adults, pediatric AR can easily induce ocular itching, sinusitis, otitis media, bronchial asthma, and even apnea syndrome, which are difficult to treat and prone to recurrence, seriously affecting children's quality of life, as well as children's poor expressive ability, which can easily lead to omission of diagnosis, misdiagnosis, and cause a great deal of trouble in the diagnosis and treatment of the disease.[3] The onset of AR is closely related to genetics, environment, mental state, living habits, age, occupation, geography, etc. Although AR is not a serious disease in itself, it has the characteristics of recurrent, prolonged, and easy to be complicated by other diseases, and if it is not treated properly, it can induce bronchial asthma, nasal polyps, allergic conjunctivitis, allergic dermatitis, sinusitis, as well as in middle-aged children. Dermatitis, sinusitis, and otitis media, which seriously affect the patient's sleep, study, and work, and even cause vocal function and facial developmental disorders, which will bring serious trouble to the patient's quality of life and a heavy economic burden, have become an important health problem worldwide.[4] AR is the commonest known chronic disease, the most prevalent in childhood. Statistically, environmental pollution, family genetic history, and changes in lifestyle habits are some of the social and family problems that can lead to the development of AR. Therefore, it is clinically important to adopt an active and effective program for symptomatic treatment.[5]

Currently, common therapeutic drugs include glucocorticoids and antihistamines.[6] Glucocorticosteroids have non-specific anti-inflammatory effects, and as the first-line drugs for the treatment of children's AR in the clinic, they are mainly used for moderate-to-severe children's AR, which can effectively improve children's nasal symptoms, and at the same time, these drugs can also reduce ocular symptoms such as tearing, redness, itching, and swelling. However, children's families struggle with appropriate clinical dosing, as well as resisting hormone drugs, and poor compliance, which can potentially contribute to undesirable effects.[7] Mometasone furoate nasal spritzer is a drug of the nasal glucocorticoid class, which is the first-line therapeutic drug recommended by the AR guidelines (2015), with a level A evidence of recommended use, and is considered to be the current preferred nasal hormone for AR in children, as well as one of the most effective medications for AR treatment.[8] Loratadine belongs to the piperidine class of antihistamine substances for AR population, which can antagonize peripheral histamine H1 receptors and alleviate various symptoms caused by allergic reactions, and it is the only second-generation H1 receptor antagonist selected in WHO and China's basic drug catalogue (2018 version), which has good efficacy and safety, but the onset of the effect is relatively slow, and after the administration of the drug, it may trigger drug side effects, and the use of this drug alone treatment is not conducive to widespread clinical dissemination.[9] Therefore, the combination of the two is often used in clinical treatment. Xie et al.[10] used mometasone furoate nasal spray in combination with loratadine pills for the treatment of AR, and obtained an overall effective rate of 93.62%, which was significantly higher than that of 78.72% for loratadine tablets alone.

In recent years, the combination of glucocorticoid nasal spray and loratadine has achieved good therapeutic effects in the treatment of AR, whereas little research has been reported on the dose of glucocorticoid nasal spray based on the simultaneous use of loratadine in the treatment of childhood AR. Consequently, the present investigation analyzed the comparative efficacy of different doses of glucocorticoid mometasone furoate nasal aerosol combined with loratadine in the treatment of rhinitis in children with a view to selecting an optimal dose that can provide a new reference therapy for clinical treatment.

MATERIALS AND METHODS

Study Design

This is a systematic clinical retrospective study to analyze and compare the efficacy of different doses of glucocorticoid nasal spray combined with loratadine in the treatment of rhinitis in children. The study population consisted of 150 pediatric rhinitis patients attending the Hospital between June 2022 and June 2024, all of whom fulfilled the clinical diagnostic criteria for pediatric rhinitis and were excluded from the study because of allergy to glucocorticoids or loratadine, and the presence of severe cardiac, hepatic, and renal diseases. The patients were divided into three groups according to the treatment modality, with 50 patients in each group. Group I was the low-dose group, which was treated with low-dose glucocorticoid nasal spray combined with loratadine; group II was the medium-dose group, which was treated with medium-dose glucocorticoid nasal spray combined with loratadine; and group III was the high-dose group, which was treated with high-dose glucocorticoid nasal spray combined with loratadine. The study was not blinded because the physician had to adjust the assessment details with the real-time feedback from the children to ensure that the results were in line with the actual clinical situation. Data on immune function, inflammatory factor levels, nasal symptom scores, quality of life scores, and the occurrence of adverse effects were collected before and after treatment, and analyzed using appropriate statistical methods to compare the efficacy and safety of the different treatment regimens.

Criteria for Selection

Inclusion Criteria

(1) Patients meeting the standards for determining this type of disease in the "Diagnosis and Treatment of Allergic Rhinitis in Children - Clinical Practice Guidelines"[11]; (2) Those who had not received specific immunotherapy in the last month or used other drugs that might interact with the trial drugs in the last 1 week; (3) Those with normal cognitive function; (4) Patients and their families signed an informative consents agreement, and the research was reviewed and approval was granted by the hospital's ethical commission.

Exclusion Criteria

(1) Not meeting the above included criterion; (2) Those who have severe nasal septum deviation, chronic rhinosinusitis with polyps, bronchial asthma, upper respiratory tract infections, lung infections, etc.; (3) Those who have serious dysfunctions of the heart, liver, kidneys, etc., or those who have autoimmune diseases; (4) Those who have high sensitivity and are allergic to the trial drugs and ingredients; (5) Those who have major neurological or psychiatric diseases and are unable to take the drugs regularly; (6) Others who are not eligible for the study.

General Information

One hundred fifty children with AR received from August 2022 to August 2024 were selected and classified into three groups of 50 patients per group based on different treatment protocols. Group I: 23 males and 27 females, age 6–14 years, mean age 9.28 ± 1.95 years. Mean disease stage 1–6 years, meant to be 3.04 ± 0.88 years. Group II: 26 males, 24 females, age 6–14 years, mean age 9.48 ± 1.66 years. Mean disease stage 1–6 years, meant to be 3.21 ± 0.79 years. Group III: 24 males, 26 females, age 6–14 years, mean age 9.34 ± 1.81 years. Mean disease stage 1–6 years, meant to be 3.18 ± 0.63 years.

Treatments

Patients in the three groups received loratadine and other conventional treatments, loratadine tablets (Keratan, 10 mg/tablet×12 tablets, Bayer Pharmaceuticals Shanghai Co, Ltd, State Pharmaceutical License H10970410). Dosage and administration: oral, once a day, 1 tablet for children weighing > 30 kg; half a tablet for children weighing≤30 kg.

On this basis, patients in all three groups were treated with budesonide nasal spray. Mometasone furoate nasal spray (specification: 50 μg/spray, concentration of drug solution 0.06% g/g, Hangzhou Minsheng Pharmaceutical Group Co., Ltd, Drug Registration Certificate No. X20000258), forming a spray when used. Group I was a low-dose group, and the children were sprayed once in each nostril in the evening. Group II was a medium dose group, where the children were sprayed once in each nostril in the morning and once in the evening. Group III was a high-dose group, in which children were sprayed once in each nostril in the morning, once at noon, and once in the evening.

All three groups of children underwent clinical treatment for 30 days. At the same time, the children were corrected for water-electrolyte disorders, acid-base

imbalance, etc., prohibited from contacting allergens, and maintained good living habits.

Therapeutic Efficacy Evaluation Indexes

Immune Function

According to the method of Rodríguez-Penedo et al.[12] with modification, the immune function indexes were observed in three groups of patients, 5 mL of elbow vein blood specimen was drawn in the morning on an empty stomach, centrifuged at 3000 r/min and 10 minutes for processing, and the supernatant was taken after serum separation, and the serum specimen was tested in the enzyme-linked immunosorbent assay (ELISA) method uniformly by the Department of Laboratory of our hospital, and the level of the patients' serum test indexes was recorded respectively after treatment. The percentage of $CD4^+$ and $CD8^+$ T cells and IgE content in serum were analyzed by Human $CD4^+$ T cells ELISA kit (JKbio 14552, Shanghai Jingkang Bioengineering Co., Ltd.), Human $CD8^+$ T cells ELISA kit (JKbio 14553, Shanghai Jingkang Bioengineering Co., Ltd.), and Human IgE ELISA Kit (EH0416, Wuhan Fine Biotech Co., Ltd.), respectively.

Inflammatory Factor Indicators

According to the research method of L. Li et al.,[13] the inflammatory indexes of children's serum were detected, children's venous blood was extracted, centrifuged at a high speed of 3500 r/min, with a radius of 10 cm, and the time was 10 minutes, and the supernatant was taken after serum separation, and serum specimens were detected by the laboratory department of our hospital using the ELISA method in a unified way to record the levels of serum inhibitory elements interleukin-6 (IL-6), interleukin-10 (IL-10), and interleukin-17 (IL-17) levels were recorded pre- and post- treatment.

Quantification of Nasal Endoscopy

The Lund-Kennedy score[14] was performed on the children. Scoring criteria: (1) polyp: 0 for no polyp, 1 for mid-nasal polyp only, and 2 for mid-nasal polyps; (2) oedema: 0 for no oedema, 1 for milder, and 2 for serious; (3) 0 for no leakage, 1 for transparent and dilute leakage, and 2 for mucous and purulent leakage. Each side is 0-10 points, and the total score is 0-20 points.

Scoring of Nasal Symptoms

The severity of nasal symptoms (including rasping, irritated nose, sniffling, rhinorrhea, constipation) pre- and post-treatment in the three groups of children was scored with reference to the scoring criteria of the "Principles of Diagnosis and Treatment and Recommended Protocols for Allergic Rhinitis".[15]

Table 1. Rhinitis symptom grading scoring criteria

Score	Sneezes, number/times	Itchy nose	Runny nose, nose blowing/d	Stuffy nose
0	None	None	None	None
2	3-5	Interstitial	≤5	During conscious inspiration
4	6-10	Ants row sensation, tolerable	5-9	Intermittent or alternating
6	>11	Ants row sensation, intolerable	≥10	Open-mouth breathing almost all day

Quality of Life Questionnaire (RQLQ) Scores

Rhinitis-related RQLQ scores[16] were administered to the three groups of children, with self-assessment questionnaires on sleep, daily activities, rhinitis-related behaviour, emotions, and eye symptoms. The rating range for this questionnaire is 0-6 points, and the rating will be based on the corresponding situation. The total score is calculated by accumulating the scores of each subfield item, with higher scores indicating worse quality of life.

Clinical Efficacy

The clinic effectiveness of the three groups of patients was determined as follows: obvious efficacy: the children's clinical symptoms basically disappeared after treatment, and there was no recurrence of rhinitis

within 3 months after treatment; effective efficacy: the children's clinical symptoms were significantly reduced, and the number of recurrence of rhinitis was significantly reduced; ineffective efficacy: there was no change in the clinical symptoms and the number of episodes of rhinitis in the children, or even there was a tendency to aggravate the symptoms. The evaluation process was completed by two experienced pediatric otolaryngologists, who received unified training before the evaluation to ensure consistency in the scoring criteria.

Incidence of Adverse Events

The incidence of adverse events was analyzed by counting the number of patient cases in which diarrhea, nausea and vomiting, gastrointestinal cramps, and headache occurred during treatment.

Treatment Compliance

In this study, we assessed and documented adherence in multiple ways: first, a daily medication punch card system was set up, whereby the guardian recorded the time and dosage of the child's medication through the hospital's proprietary app; second, telephone follow-up visits were conducted every 2 weeks to inquire about medication administration and answer questions; and third, the residual medication was recovered at the end of the treatment period, and the ratio of the actual amount of medication administered to the amount prescribed was calculated.

Sample Size Calculation

Power analysis was performed to calculate the sample size according to the G*Power 3.1.9.7 computer software to determine the sample size required to detect a statistically significant difference. Based on the primary outcome of clinical efficacy, taking into account an alpha level of 0.05 and 85% efficacy, we calculated that a sample size of 41 patients was required for each group. Considering the potential uncertainties, a sample size of 50 cases per group was chosen for this study, and we believe that the sample size of this study allows for reliable conclusions to be drawn.

Statistical Methods

SPSS 27.0 statistical software was used for data analysis. The data in this study were tested for normal distribution. Baseline characteristics were described as the number of persons and variables (expressed as mean ± SD). The results of immune function, inflammatory factor index, Quantification of nasal endoscopy, nasal symptom scores, and RQLQ index scores in the results were expressed as mean ± SD. Comparison between the two groups was tested using an independent samples t-test. Clinical efficacy, incidence of adverse effects, and treatment adherence in the results were expressed as proportions (%). Comparison between the 2 groups was analyzed using the χ^2 test. All statistical tests were two-sided, and $p<0.05$ indicated a statistically significant difference.

RESULTS

Basic Information

One hundred fifty patients participated in this study. All three groups of patients (n = 50) were administered mometasone furoate nasal spray and loratadine, a combined antihistamine medication, and were observed in groups according to the different dosages of mometasone furoate nasal spray. In that group, I was the hypodose group, group II was the mesodose group, and group III was the hyperdose group. The baseline characteristics among group two were comparable, as shown in Table 2. These results indicate that the groups were well-matched between the two pairs in terms of baseline characteristics, minimizing the risk of confounding variables that could affect the study results.

Immune Function

The outcomes of contrasting various immunological functional indexes of the three groups of patients are presented in Table 3. No obvious discrepancies were found in the immunological functional indexes of the three groups of patients' pre-treatment, and the percentages of $CD4^+$ and $CD8^+$ T cells of the three groups post-treatment were markedly above pre-treatment, and the IgE content was below pre-treatment ($p<0.05$). Post-treatment, the immune function indexes of group II and III were preferred to group I ($p<0.05$), and no marked discrepancy was recorded for group II and III ($p>0.05$).

Table 2. Baseline characteristics of patients in each group

Parameter	I (n=50)	II (n=50)	III (n=50)	I and II *p*/ (95% CI)	II and III *p*/ (95% CI)	I and III *p*/ (95% CI)
Age, y	9.28 ± 1.95	9.48 ± 1.66	9.34 ± 1.81	0.582 (-0.595, 0.195)	0.688 (-0.235, 0.515)	0.874 (-0.465, 0.345)
Gender, Male/Female	23/27	26/24	24/26	0.548	0.689	0.841
Weight, kg	33.82 ± 4.17	33.35 ± 3.65	33.90 ± 4.18	0.550 (-0.380, 1.320)	0.485 (-1.401, 0.301)	0.924 (-0.896, 0.896)
Disease duration, y	3.04 ± 0.88	3.21 ± 0.79	3.18 ± 0.63	0.312 (-0.351, 0.011)	0.834 (-0.128, 0.188)	0.363 (-0.314, 0.034)

Table 3. Comparison of immune functions (mean ± SD)

Norm	Time	I (n=50)	II (n=50)	III (n=50)	I and II *p*/ (95% CI)	II and III *p*/ (95% CI)	I and III *p*/ (95% CI)
$CD4^+$ T cells, %	Pre-treatment	30.11 ± 2.40	30.09 ± 2.51	30.32 ± 2.37	0.968 (-0.508, 0.548)	0.639 (-0.755, 0.295)	0.661 (-0.722, 0.302)
	Post-treatment	35.49 ± 2.81[a]	48.25 ± 3.88[a]	48.94 ± 3.35[a]	<0.001 (-13.529, -11.992)	0.344 (-1.478, 0.098)	<0.001 (-14.126, -12.775)
$CD8^+$ T cells, %	Pre-treatment	23.52 ± 2.37	23.37 ± 1.83	23.35 ± 1.98	0.724 (-0.322, 0.622)	0.958 (-0.391, 0.431)	0.698 (-0.308, 0.648)
	Post-treatment	31.62 ± 3.26[a]	38.51 ± 2.92[a]	39.13 ± 3.65[a]	<0.001 (-7.559, -6.221)	0.351 (-1.350, 0.110)	<0.001 (-8.259, -6.762)
IgE, g/L	Pre-treatment	404.59 ± 9.03	404.73 ± 9.68	404.32 ± 7.60	0.941 (-2.155, 1.875)	0.814 (-1.520, 2.340)	0.872 (-1.552, 2.092)
	Post-treatment	360.36 ± 15.76[a]	269.89 ± 9.89[a]	269.40 ± 10.34[a]	<0.001 (87.334, 93.606)	0.809 (-1.685, 2.665)	<0.001 (87.835, 94.086)

[a] Designates marked variances versus pre-treatment, $p<0.05$. CI: confidence interval; IgE: immunoglobulin E.

Inflammatory Factor Indicators

The outcomes of the comparisons of inflammatory factor indexes among the 3 groups of patients are presented in Table 4. No remarkable differences were observed in the indices of the three groups of patients' pre-treatment. The IL-6 and IL-17 contents of the three groups were remarkably above the pre-treatment and the IL-10 contents were below the pre-treatment levels ($p<0.05$). Post-treatment, the comparative specifications of inflammatory factors in groups II and III were outperforming group I ($p<0.05$), and no marked discrepancies were recorded among groups II and III ($p>0.05$).

Quantification of Nasal Endoscopy

The outcomes of the comparisons of Lund-Kennedy ratings of the three groups of patients are summarized in Table 5, and the discrepancies among the three groups of patients' ratings pre-treatment were not academically meaningful ($p<0.05$). Post-treatment, the ratings of group II and III were below those of group I ($p<0.05$), and no marked discrepancies were noted between group II and III ($p>0.05$).

Table 4. Indicators of inflammatory factors (mean ± SD, pg/mL)

Norm	Time	I (n=50)	II (n=50)	III (n=50)	I and II *p*/ (95% CI)	II and III *p*/ (95% CI)	I and III *p*/ (95% CI)
IL-6	Pre-treatment	20.34 ± 2.14	20.42 ± 2.09	20.21 ± 1.43	0.850 (-0.534, 0.374)	0.559 (-0.204, 0.624)	0.722 (-0.294, 0.554)
	Post-treatment	13.53 ± 2.28[a]	6.81 ± 2.04[a]	6.67 ± 2.05[a]	<0.001 (6.252, 7.188)	0.733 (-0.299, 0.579)	<0.001 (6.392, 7.329)
IL-10	Pre-treatment	56.21 ± 4.20	56.27 ± 3.54	56.18 ± 3.46	0.939 (-0.909, 0.789)	0.898 (-0.662, 0.842)	0.969 (-0.814, 0.874)
	Post-treatment	63.73 ± 3.54[a]	68.11 ± 3.42[a]	68.42 ± 2.96[a]	<0.001 (-5.128, -3.632)	0.629 (-1.005, 0.385)	<0.001 (-5.403, -3.977)
IL-17	Pre-treatment	49.89 ± 4.24	49.61 ± 3.97	49.79 ± 3.73	0.734 (-0.604, 1.164)	0.816 (-1.009, 0.649)	0.901 (-0.766, 0.966)
	Post-treatment	41.01 ± 4.04[a]	30.08 ± 3.97[a]	29.95 ± 2.72[a]	<0.001 (10.070, 11.790)	0.849 (-0.656, 0.916)	<0.001 (10.260, 11.860)

[a]Designates marked variances versus pre-treatment, $p<0.05$. [b]CI: confidence interval; IL: interleukin.

Table 5. Comparison of Lund-Kennedy (mean ± SD, score)

Time	I (n=50)	II (n=50)	III (n=50)	I and II *p*/ (95% CI)	II and III *p*/ (95% CI)	I and III *p*/ (95% CI)
Pre-treatment	9.92 ± 1.16	9.94 ± 1.21	9.79 ± 1.44	0.933 (-0.275, 0.235)	0.574 (-0.141, 0.441)	0.620 (-0.158, 0.418)
Post-treatment	3.48 ± 0.58[a]	2.23 ± 0.37[a]	2.17 ± 0.53[a]	<0.001 (1.135, 1.365)	0.513 (-0.045, 0.165)	<0.001 (1.190, 1.430)

[a]Designates marked variances versus pre-treatment, $p<0.05$. [b]CI: confidence interval.

Nasal Symptom Scores

The results of the nasal symptom scores of the children in the three groups are presented in Table 6, and no marked discrepancies in the symptom scores of the children in the three groups pre-treatment ($p>0.05$), and the scores of the children post-treatment were below than pre-treatment ($p<0.05$). Post-treatment, the scores of group II and III were above to group I ($p<0.05$), and no marked discrepancies between group II and III ($p>0.05$).

RQLQ Index Scores

The results of the RQLQ index scores of the children in the three groups are summarized in Table 7, and no marked discrepancies in the symptom scores of the children in the three groups pre-treatment ($p>0.05$), and the scores of all the scores were below pre-treatment ($p<0.05$). Post-treatment, the scores of groups II and III were above to group I ($p<0.05$), and no marked discrepancies between group II and III ($p>0.05$).

Clinical Efficacy

The clinical efficacy of the children in the three groups was analyzed are summarized in Table 8. Post-treatment, the efficacy of both group II and III was above that of group I ($p<0.05$), and no marked discrepancies between group II and III ($p>0.05$).

Incidence of Adverse Events

Adverse events of varying degrees occurred during treatment in all three groups are summarized in Table 9, the incidence of adverse events was 18% (9/50), 8% (4/50), and 6% (3/50) in group I, II, and III, respectively, and the incidence of adverse events in group II and III was below in group I ($p<0.05$), and no marked discrepancies among group II and III ($p>0.05$).

Table 6. Nasal symptom scores (mean ± SD, score)

Norm	Time	I (n=50)	II (n=50)	III (n=50)	I and II *p*/ (95% CI)	II and III *p*/ (95% CI)	I and III *p*/ (95% CI)
Sneeze	Pre-treatment	3.12 ± 0.86	3.08 ± 0.77	3.23 ± 0.66	0.807 (-0.136, 0.216)	0.298 (-0.306, 0.006)	0.475 (-0.281, 0.061)
	Post-treatment	2.13 ± 0.69[a]	1.52 ± 0.60[a]	1.48 ± 0.43[a]	<0.001 (0.470, 0.750)	0.702 (-0.079, 0.159)	<0.001 (0.513, 0.787)
Itchy nose	Pre-treatment	4.18 ± 0.96	4.13 ± 1.20	4.28 ± 1.36	0.819 (-0.190, 0.290)	0.560 (-0.428, 0.128)	0.672 (-0.369, 0.169)
	Post-treatment	2.28 ± 0.56[a]	1.59 ± 0.52[a]	1.57 ± 0.42[a]	<0.001 (0.574, 0.806)	0.833 (-0.084, 0.124)	<0.001 (0.599, 0.821)
Runny nose	Pre-treatment	4.59 ± 1.49	4.51 ± 1.46	4.56 ± 1.49	0.787 (-0.237, 0.397)	0.866 (-0.367, 0.267)	0.920 (-0.290, 0.350)
	Post-treatment	2.10 ± 1.12[a]	1.69 ± 0.44[a]	1.62 ± 0.43[a]	<0.05 (0.169, 0.651)	0.423 (-0.023, 0.163)	<0.05 (0.238, 0.722)
Stuffy nose	Pre-treatment	4.24 ± 1.03	4.05 ± 0.98	4.09 ± 0.77	0.347 (-0.026, 0.406)	0.821 (-0.235, 0.155)	0.412 (-0.054, 0.354)
	Post-treatment	2.65 ± 0.96[a]	2.09 ± 0.64[a]	1.98 ± 0.48[a]	<0.001 (0.370, 0.750)	0.333 (-0.017, 0.237)	<0.001 (0.473, 0.867)

[a]Designates marked variances versus pre-treatment, $p<0.05$. [b]CI: confidence interval.

Table 7. Comparison of RQLQ index scores (mean ± SD, score)

Norm	Time	I (n=50)	II (n=50)	III (n=50)	I and II *p*/ (95% CI)	II and III *p*/ (95% CI)	I and III *p*/ (95% CI)
Sleep	Pre-treatment	5.98 ± 0.74	5.96 ± 0.84	5.94 ± 0.67	0.900 (-0.152, 0.192)	0.896 (-0.148, 0.188)	0.778 (-0.112,0.192)
	Post-treatment	4.85 ± 0.54[a]	4.24 ± 0.58[a]	4.01 ± 0.77[a]	<0.001 (0.489, 0.731)	0.095 (0.077, 0.383)	<0.001 (0.688, 0.992)
Daily activities	Pre-treatment	11.14 ± 1.24	11.33 ± 0.93	11.21 ± 1.12	0.388 (-0.436, 0.056)	0.561 (-0.121, 0.361)	0.768 (-0.333,0.193)
	Post-treatment	10.31 ± 1.04[a]	8.86 ± 0.92[a]	8.58 ± 1.08[a]	<0.001 (1.234, 1.666)	0.166 (0.061, 0.499)	<0.001 (1.502, 1.958)
Rhinitis-related behavior	Pre-treatment	9.95 ± 0.96	9.94 ± 1.01	9.99 ± 1.05	0.960 (-0.202, 0.222)	0.809 (-0.271, 0.171)	0.843 (-0.257,0.177)
	Post-treatment	8.21 ± 0.82[a]	7.72 ± 0.60[a]	7.63 ± 0.50[a]	<0.001 (0.328, 0.653)	0.417 (-0.031, 0.211)	<0.001 (0.416, 0.744)
Emotions	Pre-treatment	7.55 ± 0.65	7.58 ± 0.54	7.54 ± 0.58	0.802 (-0.161, 0.101)	0.722 (-0.081, 0.161)	0.936 (-0.123,0.143)
	Post-treatment	5.99 ± 0.24[a]	5.22 ± 0.33[a]	5.21 ± 0.34[a]	<0.001 (0.705, 0.835)	0.882 (-0.062, 0.082)	<0.001 (0.713, 0.847)
Eye symptoms	Pre-treatment	5.19 ± 0.73	5.07 ± 0.56	4.98 ± 0.54	0.359 (-0.025, 0.265)	0.415 (-0.028, 0.208)	0.105 (0.065, 0.355)
	Post-treatment	4.11 ± 0.40[a]	3.64 ± 0.37[a]	3.61 ± 0.34[a]	<0.001 (0.387, 0.553)	0.674 (-0.047, 0.107)	<0.001 (0.419, 0.581)

[a]Designates marked variances versus pre-treatment, $p<0.05$.

[b]CI: confidence interval; RQLQ: Quality of Life Questionnaire.

Table 8. Comparison of clinical efficacy

Group (*n*=50)	Visible effect	Effective	Ineffective	Overall effective rate
I	9	21	20	30（60%）
II	12	25	13	37（74%）
III	13	25	12	38（76%）
I and II χ^2/p	4.4432/<0.05			
II and III χ^2/p	0.107/0.744			
I and III χ^2/p	5.882/<0.05			

Table 9. Comparisons of the incidence of adverse reactions

Group (*n*=50)	Nose/throat dryness	Nausea and vomiting	Gastrointestinal cramps	Headache	Overall incidence
I	2	2	3	2	9（18%）
II	1	1	1	1	4（8%）
III	1	1	1	0	3（6%）
I and II χ^2/p	4.421/<0.05				
II and III χ^2/p	0.307/0.579				
I and III χ^2/p	6.818/<0.05				

Treatment Compliance

The results showed that the treatment compliance of groups I, II, and III was 92% (46/50), 96% (48/50), and 94% (47/50), respectively. Indicating that the compliance levels of the three groups are similar and no significant statistical differences were found (p>0.05).

DISCUSSION

AR is an inflammatory disorder of the nasal mucosa caused by an overactive immune system, and the main clinical symptoms include an itchy nose, rhinorrhea, sniffling, and paroxysmal sneezing. In recent years, the number of children suffering from AR has increased.[17] The incidence of AR in children is significantly higher than in adults, which is related to the immune function of children, and the pathogenesis of AR in children is very complex. Children with AR usually present with oedema of the nasal turbinates, covered with a watery mucus, which is usually purple or pale in color. If AR is not treated in a timely manner, it may develop into sinusitis or even bronchial asthma, which may have a serious impact on the child's physical and mental health.[18] As far as we know, there is no complete cure for AR, and the main goal of clinical treatment is to effectively control AR, reduce the episodes of rhinosinusitis AR, and improve the quality of life of children.[19]

Loratadine is a novel long-acting antihistamine drug that selectively antagonizes peripheral histamine H1 receptors and maintains mast cell stability, while the nitrogen substituent contained therein reduces the lipophilicity of the drug and inhibits the central nervous system, thus achieving a reduction in the role and effect of adverse effects.[20] However, previous clinical results and empirical analyses have shown that a single application of loratadine is not significantly effective in AR, and loratadine is a tablet drug, which is inconvenient for children to take orally, thus seriously affecting medication adherence and compromising efficacy in children.[21] Mometasone furoate nasal spray belongs to the third generation of nasal corticosteroid

hormones, which acts on the local mucosa of the nasal cavity and has a very low bioavailability, making it the drug of choice for the treatment of AR, and can be used in younger children aged 3 years and above. Its anti-inflammatory, anti-allergic, and anti-oedema effects are remarkable, and it can effectively treat various inflammatory diseases. It can rapidly and permanently control the state of acute inflammatory episodes, thus providing rapid symptomatic relief.[22] In addition, direct stimulation of the glucocorticoid receptor sites in the nasal mucosa with high concentrations of the administered drug can activate the receptors more quickly and achieve therapeutic efficacy.[23] The mechanism of action is to reduce the release of local inflammatory factors or mediators in the nasal cavity by inhibiting the recruitment of immune cells, which has a significant effect in stabilizing endothelial cells, smooth muscle cells, and lysosomal membranes, and it also significantly reduces the production of IgE, and achieves a suppression of inflammatory responses.[24] Mometasone furoate nozzle sprays are demonstrated to significantly reduce and improve the clinical symptoms of sneezing, stuffiness, and runny nose in children with AR. From the point of view of drug usage, Mometasone furoate nasal spray is a spray, directly sprayed on the nose, which can directly act on the nasal mucosa and directly exert the local anti-inflammatory effect of the drug, and the drug basically does not cause systemic effects, which is well tolerated and has a high degree of acceptance and adherence by the children.[25] Consequently, the combination of mometasone furoate nasal spray combined with loratadine for the therapy of AR in children remarkably improves clinical outcomes.

The findings showed that the combination of mometasone furoate nasal spray and loratadine antihistamine has a certain therapeutic effect on the treatment of AR, but the efficacy of mometasone furoate nasal spray varies with different doses. In terms of the effect on immune cells and inflammatory factors, the treatment could effectively enhance the percentage of $CD4^+$ and $CD8^+$ T cells and IL-10 content in the serum of the children, and reduce the content of IgE, IL-16, and IL-17 indicators ($p<0.05$). Comparatively, children in groups II and III showed better results than those in group I ($p<0.05$). No remarkable discrepancy in results among groups II and III ($p>0.05$), which may be due to the fact that the optimal therapeutic effect has been achieved at this dose. It is also shown that medium-dose mometasone furoate nasal spray combined with loratadine in the treatment of AR can improve the immune ability of the body, and at the same time, effectively regulates the inflammatory cells, inhibits the expression of inflammatory factors, and alleviates the adverse effects of inflammatory reactions on respiratory function. Combining the Lund-Kennedy score, nasal symptom score, and RQLQ index score, we can observe that the indexes of children in group II and III are above to group I ($p<0.05$), while no remarkable discrepancy among the indices results of group II and III ($p>0.05$), which indicates that the treatment method has good therapeutic effect in the treatment of AR. There were no significant differences in adherence to treatment among the three groups, which also indicates that different doses of glucocorticoid nasal spray combined with loratadine treatment regimens were equally well accepted and implemented in the pediatric population, and did not significantly affect the medication compliance of the children and their guardians due to the difference in dosage. In order to save cost, we recommend the medium-dose of mometasone furoate nasal spray and loratadine combined with an antihistamine for the treatment of AR. Andrews et al.[26] reported similar findings in the olopatadine-mometasone combination nasal spray for seasonal AR study. In addition, clinical efficacy assessment and occurrence of adverse effects were recorded in three groups of children, and the results reaffirmed the effectiveness of medium-dose mometasone furoate nasal spray combined the loratadine as an antihistamine for the treatment of AR. These results suggest that the combination of moderate-dose mometasone furoate nasal spray, combined with loratadine, in the treatment of AR can further improve the clinical symptoms and quality of life of patients.

This study still has some limitations. Firstly, the follow-up period of the study was only 30 days, and for chronic diseases such as AR, the short-term efficacy results cannot fully reflect the long-term therapeutic effect. The recurrence of symptoms after stopping the drug and the continuous changes of immunological indexes have not been clarified, so the short-term observation cannot be equated with the long-term changes of immunological indexes caused by allergen immunotherapy, which still need to be observed by extending the follow-up period. Secondly, the study population came from a single center, and the geographical characteristics and case composition of the sample may be limited, so the results should be

extrapolated to other regions or different treatment settings with caution. Although the study evaluated several immunological and clinical indicators, it lacked an in-depth exploration of the mechanism of action of the combination therapy, such as the synergistic pathways between glucocorticoids and loratadine in regulating immune cell function and inflammatory factor balance, which may limit the judgment of the direction of optimization of the therapeutic regimen. Considering individual differences such as lifestyle habits, regarding adverse reactions, we only observed whether they occurred or not, to further assess the extent of their occurrence. In addition, the study did not set up groups with different durations of combination medication to determine the optimal treatment course and lacked a direct comparison with other treatment options (e.g., nasal antihistamine combined with glucocorticoid), which made it difficult to comprehensively assess the clinical advantages of this regimen. Lastly, some of the indicators were not assessed by a more specific child assessment scale, which may affect the accuracy of the results.

In this study, we analyzed different doses of mometasone furoate nasal spray combined with loratadine for the treatment of AR, and the results of the combination of various test indices showed that all the results of the three groups of patients were better than the pre-treatment results after treatment. After treatment, the percentage of $CD4^+$ and $CD8^+$ T cells, IL-10 content, and clinical efficacy in group II and III remarkable above in group I, while the IgE content, IL-6 and IL-17 content, quantitative Lund-Kennedy score of nasal endoscopy, children's nasal symptom scores, RQLQ scores, and the incidence of adverse events were below in group I ($p<0.05$). No remarkable discrepancy in the changes in indicators among patients in groups II and III after treatment ($p>0.05$). The results showed that the combination of mometasone furoate nasal spray, combined with loratadine at different doses, was effective in the treatment of AR, which could effectively improve the cellular immune function and symptom score of the children, and improve the quality of life. Combining the therapeutic effects of different doses, we recommend the use of medium-dose mometasone furoate nasal spray with loratadine as a combination antihistamine for the treatment of AR, which is worth promoting and widely used in the clinic. However, the present study has the shortcomings of a small sample size and short treatment period; due to the limitations of conditions, more specific inflammatory indices, such as others, could not be included. Multi-centre, large-sample, high-quality clinical studies can be carried out in the future for validation. Long-period follow-up was not performed in this study to determine the long-term effectiveness of the patients, and will continue to be performed in the future to determine the long-term outcomes of the patients.

STATEMENT OF ETHICS

This experiment was approved by School of Nursing, Heilongjiang University of Traditional Chinese Medicine Ethics Committee. (NO. 2023-10-A21).

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None.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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Not applicable.

DATA AVAILABILITY

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

AI ASSISTANCE DISCLOSURE

No artificial intelligence tools were utilized during the preparation of this manuscript.

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