Original Article
Randomized controlled study of desloratadine citrate and loratadine in the treatment of allergic rhinitis

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Abstract: Objective: To observe the clinical efficacy and safety of desloratadine citrate disodium in the treatment of allergic rhinitis (AR). Methods: 200 patients with AR treated at otorhinolaryngology department of Sichuan Provincial People’s Hospital from January, 2012 to October, 2014 were selected for this study. They were randomly divided into therapeutic group and control group with 100 patients in each. And there was no obvious difference in general data between two groups. The therapeutic group was treated with desloratadine citrate disodium tablets with daily dosage of 8.8 mg by oral administration, while the control group was given loratadine with daily dosage of 10 mg by oral administration. The treatment course was one month. All the patients were not given corticosteroids and other antihistamines. Observe symptoms before and after the treatment, signs score and clinical efficacy in two groups. We intraperitoneal injected 100 µg of ovalbumin 2 times to build sensitized model in ICU mic and separated splenic lymphocyte; pretreated with 1.5 mol/L esloratadine citrate disodium and loratadine, and then added 200 mg/L ovalbumin for stimulation; the influence of esloratadine citrate disodium and loratadine on lymphocyte releasing prostaglandin E2, leukotrienes, interleukin-4, interleukin-5 and tumor necrosis factor were detected and compared by ELISA method. Results: In the 99 cases selected in therapeutic group, 58 cases were markedly effective, 34 cases were effective, 7 cases were ineffective, and the total effective rate was 92.9%. In the 98 cases selected in control group, 7 cases were markedly effective, 48 cases were effective, 23 cases were ineffective, and the total effective rate was 76.5%. There was statistically significant difference in the total effective rate between the two groups (P<0.05). In mouse sensitization model, compared with those in the loratadine group, desloratadine citrate disodium could significantly decrease the levels of lymphocytes releasing PGE\(_2\), LTB\(_4\), IL-4, IL-5, TNF-α. Conclusion: Compared with loratadine, the clinical efficacy of desloratadine citrate disodium tablets is better in the treatment of AR and with good safety.

Keywords: Desloratadine citrate disodium, loratadine, allergic rhinitis, efficacy

Introduction

Allergic rhinitis (AR) is a disease seriously affecting patients’ quality of life; domestic investigation [1] shows that AR patients accounted for 1/5 of otorhinolaryngology outpatient, and 1/3 of total nasal sinus disease outpatients, it has become one of the most common diseases in otorhinolaryngology department. AR and bronchial asthma belong to the IgE-mediated allergic airway inflammation, both of them are closely related and often coexist in the same patient [2, 3]. 40% of AR patients can be combined with bronchial asthma [4]. In recent years, the incidence of the disease is increasing year by year. Although the disease generally does not need to be hospitalized and will not cause life risk, it seriously affects patients’ life quality and reduces work efficiency [5, 6]. If not treated in time, it may cause many other complications, such as sinusitis, secretory otitis media, asthma, stress and anxiety.

H1-antihistamine is one of the main drugs to treat AR, it’s a kind of drug blocking histamine on H1 receptor levels (inverse agonist), and some of them also have anti-allergic inflammation characteristics. It is mainly used in the early stage of AR, and can relieve sneezing, itchy nose, runny nose, and even nasal obstruction symptoms [7, 8]. Loratadine is a new receptor antagonist antihistamine with no drowsiness effect, it does not affect the patient’s
behavior, work and life quality, and has good
treatment effect at early response; however, it
has limited efficacy in nasal congestion [9].
Based on a single component of desloratadine
compounds, desloratadine citrate is made from
the reaction of desloratadine and disodium
hydrogen citrate, it is the third-generation anti-
histamines with higher water solubility, rapid
onset, superior bioavailability. The relationship
between desloratadine citrate and loratadine is
not a simple replacement of acid radical or salt
base. They are two completely different com-
pounds with great difference in physical and
chemical properties, to further evaluate clinical
efficacy and safety of desloratadine citrate in
treatment of allergic rhinitis, from January,
2012 to October, 2014, our department applied
desloratadine citrate (trade name: Beixue,
Yangtze River Pharmaceutical Group) and
loratadine (trade name: Clarityne, Shanghai
Schering-Plough Pharmaceutical Co., Ltd) in
treating allergic rhinitis of 200 cases, and com-
pared its efficacy, adverse reactions, and other
related issues.

Materials and methods

Clinical data

200 AR patients treated at otorhinolaryngology
department of Sichuan Provincial People’s
Hospital from January, 2012 to October, 2014
were collected in this study, they were aged
from 18 to 60 with a median age of (43.2±5.8),
in which 126 cases were male, 74 cases were
female. Inclusion criteria: (1) a diagnosis of
patients with allergic rhinitis in accordance with
the 2009 Wuyi Mountain
conference diagnostic
criteria which formulated by
Chinese Medical Associ-
ation of Otorhinolaryn-
gology, Head and Neck Sur-
gery branch. (2) age ≥18;
(3) history of rhinitis ≥2
years. Exclusion criteria: (1)
applied other antihista-
mines and corticosteroids
in 2 weeks; (2) combined
use of imidazole antifungal
drugs, macrolide antibiot-
ics, sedatives, corticoste-
roids, immunomodulatory
drugs, anticholinergic age-
nts, beta receptor agonist
and other drugs; (3) allergic
to this medicine; (4) organic heart disease,
arrhythmia, recently had chronic gastrointestinal,
levek, kidney disease or other serious dis-
eases; (5) the positive pregnancy or lactating
women, women at childbearing age who planed
to reproduce in near future, driver, mechanical
workers and high-altitude operators; (6) urti-
caria caused by physical stimulus (pressure,
cold, sunlight etc.), cholinergic urticaria, serum
disease urticaria, vasculitis urticaria, heredi-
tary vascular edema, other diseases (such as
SLE, thyroiditis) induced urticaria; (7) people
can not complete the treatment program and
follow up according to the requirements. The
study was approved by the hospital ethics com-
mittee and consent papers were signed and
obtained from all the patients. The basic infor-
mation of patients is shown in Table 1.

The method of treatment

According to the random number table, we
divided 200 patients into observation group
and control group with 100 in each group. The
observation group consisted of 43 cases of
male, 57 cases of female, and was given deslo-
ratadine citrate disodium tablets (Beixue
Yangtze River Pharmaceutical Group) and
loratadine (trade name: Clarityne, Shanghai
Schering-Plough Pharmaceutical Co., Ltd) in
treating allergic rhinitis of 200 cases, and com-
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patients with allergic rhinitis in accordance with

Table 1. The observation group and the control group of patients with
clinical feature

<table>
<thead>
<tr>
<th>Clinical symptoms</th>
<th>The observation group</th>
<th>The control group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>43</td>
<td>45</td>
</tr>
<tr>
<td>Female</td>
<td>57</td>
<td>55</td>
</tr>
<tr>
<td>Course of disease</td>
<td>3 months–6 years</td>
<td>5 months–9 years</td>
</tr>
<tr>
<td>With dogs or cats at home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>58</td>
<td>47</td>
</tr>
<tr>
<td>Yes</td>
<td>42</td>
<td>53</td>
</tr>
<tr>
<td>With asthma</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>23</td>
<td>27</td>
</tr>
<tr>
<td>None</td>
<td>77</td>
<td>73</td>
</tr>
<tr>
<td>Parents with AR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>18</td>
<td>14</td>
</tr>
<tr>
<td>None</td>
<td>82</td>
<td>86</td>
</tr>
</tbody>
</table>
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Po, qd, for 3 months. No corticosteroids and other antihistamine drugs were applied in both groups.

**Symptom and standards of signs score [10]**

The symptom score standard of rhinitis is shown in Table 2. Standards of signs score: the inferior turbinate was closely adjacent to basis nasi and nasal septum, without seeing the middle turbinate, or middle turbinate mucosal polypoid, polyp formation, recorded 3 points; inferior turbinate was closely adjacent to nasal septum (or basis nasi), small gap between inferior turbinate and basis nasi (or the nasal septum), recorded 2 points; mild swelling of the turbinate, nasal septum and middle turbinate is visible, recorded 1 point.

**Efficacy evaluation criteria [10]**

Treatment efficacy was evaluated according to symptoms and signs score; the scoring method:

\[ \frac{\text{pre-treatment score} - \text{post-treatment score}}{\text{pre-treatment score}} \times 100\% \]

The outcome ≥66% was considered markedly effective, 65% to 26% was effective, and ≤25% was invalid.

**Detection of serum specific IgE**

The serum allergen specific IgE antibody content of patients in each group was detected quantitatively by Western blot method before treatment. Serum specific IgE grading criteria: the positive reaction intensity was divided into 6 levels according to the content of specific IgE in serum, the grading levels can be used to predict patients with mild, moderate or severe allergic reaction (grading criteria was provided by Mediwiss company). See in Table 3.

**Adverse reactions**

Observe adverse reaction after patients using the medicine, and take auxiliary examination of ECG, urine routine, blood routine, and blood pressure etc.

**To construct the sensitized mouse model and isolate the spleen lymphocytes**

0.2 ml saline containing 100 µg egg protein (purity level of 98%) and 4 mg aluminum hydroxide was injected into ICR mice (provided by experimental animal center of Sichuan University, qualified certificate number: SCXK (Sichuan) 2009-09) in abdominal cavity, repeat the procedure 2 weeks later to construct ovalbumin sensitized mice model. After 24 h, the mice were sacrificed, their spleens were

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**Table 2. Symptoms and signs of scoring criteria**

<table>
<thead>
<tr>
<th>Grading score</th>
<th>Sneezing○</th>
<th>Runny noseΔ</th>
<th>Rhinobyon</th>
<th>Rhinocnesmus</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 point</td>
<td>3~5</td>
<td>≤4</td>
<td>breathe consciously in feeling interruption</td>
<td></td>
</tr>
<tr>
<td>2 points</td>
<td>6~10</td>
<td>5~9</td>
<td>intermittent or interactive formation but tolerable</td>
<td></td>
</tr>
<tr>
<td>3 points</td>
<td>≥11</td>
<td>≥10</td>
<td>mouth breathing all day formation but unbearable</td>
<td></td>
</tr>
</tbody>
</table>

Attention: ○Number of continuous sneezing at one time, Δthe daily times to blow nose.

**Table 3. Serum specific IgE levels**

<table>
<thead>
<tr>
<th>Specific IgE content (kUA/L)</th>
<th>Classification</th>
<th>Specific IgE levels</th>
<th>Clinical manifestation</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;0.35</td>
<td>0</td>
<td>none or no detection</td>
<td>not allergic</td>
</tr>
<tr>
<td>0.35-0.69</td>
<td>1</td>
<td>low</td>
<td>may or mild allergies</td>
</tr>
<tr>
<td>0.70-3.49</td>
<td>2</td>
<td>raise</td>
<td>light allergy</td>
</tr>
<tr>
<td>3.50-17.49</td>
<td>3</td>
<td>significantly increase</td>
<td>moderate allergic</td>
</tr>
<tr>
<td>17.50-49.9</td>
<td>4</td>
<td>higher</td>
<td>moderate or severe allergies</td>
</tr>
<tr>
<td>50-100</td>
<td>5</td>
<td>high</td>
<td>severe allergic</td>
</tr>
<tr>
<td>&gt;100</td>
<td>6</td>
<td>extremely high</td>
<td>particularly severe allergic</td>
</tr>
</tbody>
</table>

**Table 4. Comparison between observation group and control group**

<table>
<thead>
<tr>
<th>Groups</th>
<th>Cases</th>
<th>Effective</th>
<th>Valid</th>
<th>Invalid</th>
<th>Total efficiency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation group</td>
<td>99</td>
<td>58</td>
<td>34</td>
<td>7</td>
<td>92.9*</td>
</tr>
<tr>
<td>Control group</td>
<td>98</td>
<td>27</td>
<td>48</td>
<td>23</td>
<td>76.5</td>
</tr>
</tbody>
</table>

*P<0.05 vs control group.
removed out under aseptic operation and digested by trypsin for 10 min at 37°C; use 200 mesh strainer to prepare the spleen lymphocytes suspensions. 1640 culture fluid was used to subculture the lymphocytes in the 24 hole cell culture plate. The control group was intra-peritoneal injected with the same dose of normal saline.

**Detect the expression level of various inflammatory factors in cell culture supernatant**

The spleen cell suspension was prepared, and the cells were adjusted to 2×10^6/ml with 1640 culture fluid, and the suspension was added to 24 holes culture plate with 1.5 ml in each hole. Dilute desloratadine citrate disodium tablets and loratadine tablets with 1640 cell culture fluid which containing 10% fetal bovine serum, sterilization by microporous membrane. The final concentration of desloratadine citrate disodium and loratadine in each suspension was 1.5 µmol/L. After pharmacological preconditioned of desloratadine citrate claritine and loratadine, the lymphocytes suspension was stimulated by directly adding egg protein (final concentration of 200 mg/L), put it in 5% CO_2 incubator for 2 h at 37°C. Culture supernatant was collected to detect the level of LTB-4 and PG-T-2 by ELISA method; detect the level of TFN-α after 9h incubation and level of IL-4, IL-5 after 36 h incubation with the same method. Each group has 5 complex holes.

**Statistical treatment**

All data were processed by SPSS12.0 software package, and measurement data were represented by mean ± standard deviation, comparison between groups adopted single factor variance, classification data were represented by percentage, comparison between groups were examined by using χ^2, P<0.05 was considered statistically significant.

**Result**

**The levels of serum specific IgE classification in the two groups were similar before treatment**

99 effective cases were collected at the end of the observation period in the observation group, according to the grading criteria of serum specific IgE before treatment, we classified 0-2 level of 14 cases, 3-4 level of 66 cases, 5-6 level of 19 cases, and 1 dropout patients (missing follow-up on 9th day, result in incomplete data). A total 98 effective cases were collected in the control group, according to the same grading criteria, we classified 0-2 of 12 cases, 3-4 of 67 cases, 5-6 level of 19 cases, and 2 dropout cases (1 case was lost during the observation period and 1 case was excluded due to unstandardized medicine taking). There was no significant difference between the two groups before treatment (P>0.05).
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The effective rate of observation group was higher than that of control group.

The total effective rate of the observation group was 92.9% and the control group was 76.5%. The difference was statistically significant (P<0.05) in Table 4.

The symptom score of the observation group were lower than those of the control group.

Compared the pre-treatment symptom scores on runny nose, nasal congestion, sneezing, itchy nose and inferior turbinate swelling between two groups, the difference was considered no statistical significance (P>0.05). After treatment, the symptom scores of the two groups were significantly lower than before, the difference was statistically significant (P<0.05), and the observation group was lower than the control group, the difference was statistically significant (P<0.05). See in Table 5.

The incidence of adverse reactions in observation group was lower than that in control group.

We can see from Table 6, the incidence of adverse reaction in patients taking desloratadine citrate was 7%, which was significantly lower than the 16% of loratadine. In this study, adverse reactions included nausea, dizziness, headache, fatigue, drowsiness and erythra.

The expression level of LTB₄, IL-4, IL-5 and TNF-α were improved after egg protein stimulated spleen lymphocytes in mice.

Compared with the normal control group, the levels of PGE₂, LTB₄, IL-5, TNF-α, and IL-4 in ovalbumin-sensitized model group were significantly elevated (P<0.05) after stimulated by egg protein again. In Table 7, it indicated the model constructed successfully in mice.

Levels of TNF-α, LTB₄, IL-4, IL-5 and PGE₂ in spleen lymphocytes after drug treatment.

Compared with Clarityne treatment group, levels of PGE₂, LTB₄, IL-4, IL-5 and TNF-α released by allergic mice spleen lymphocytes decreased significantly in desloratadine citrate treatment group, and the difference has statistical significance. See in Table 8.

Discussion

AR is a chronic inflammatory reaction of nasal mucosa, which involves immunologically active cells and cytokines, etc. that released by IgE media after the specific individual exposed to allergens, it’s one of the common diseases in the department of otolaryngology. Epidemiological surveys show that increasing prevalence of AR is closely related to indoor air pollution [11]. H1 receptor antagonists are important drugs for the treatment of AR. The first generation of anti-histamine drugs easily leads to drowsiness, sedation and fatigue that may reduce the efficiency of learning and working, and results in abnormal sleep [12, 13]. At present, the second generation of H1 receptor antagonists, represented by Clarityne, is recommended to treat adults and pediatric allergic rhinitis (AR) [14], it has good effect in relieving histamine-mediated symptoms (runny nose, sneezing, itchy nose and eye symptoms) as well as nasal congestion [15, 16]. The past clinical researches confirmed that Clarityne can relieve seasonal AR symptoms quickly and continuously, and even efficient to moderate and severe patients [18]. Some patients may have

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Table 7. Levels of PGE₂, LTB₄, IL-4, IL-5 and TNF-α released by spleen lymphocytes of sensitized mice

<table>
<thead>
<tr>
<th>Group</th>
<th>PGE₂ (ng/L)</th>
<th>LTB₄ (ng/L)</th>
<th>IL-4 (ng/L)</th>
<th>IL-5 (ng/L)</th>
<th>TNF-α (ng/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>51.12±10.76</td>
<td>43.25±8.46</td>
<td>33.56±8.45</td>
<td>22.41±3.79</td>
<td>86.95±10.82</td>
</tr>
<tr>
<td>Model group</td>
<td>215.41±37.62*</td>
<td>179.94±42.11*</td>
<td>108.16±20.81*</td>
<td>62.51±9.63*</td>
<td>307.41±34.12*</td>
</tr>
</tbody>
</table>

Attention: *compared with control group, P<0.05.

Table 8. Level comparison of PGE₂, LTB₄, IL-4, IL-5 and TNF-α released by spleen lymphocytes of sensitized mice after treated with two drugs

<table>
<thead>
<tr>
<th>Group</th>
<th>PGE₂ (ng/L)</th>
<th>LTB₄ (ng/L)</th>
<th>IL-4 (ng/L)</th>
<th>IL-5 (ng/L)</th>
<th>TNF-α (ng/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Desloratadine citrate group</td>
<td>124.62±17.96</td>
<td>113.75±16.86</td>
<td>57.96±8.05</td>
<td>42.86±5.59</td>
<td>186.65±36.52</td>
</tr>
<tr>
<td>Clarityne group</td>
<td>183.41±17.92*</td>
<td>149.14±12.91*</td>
<td>77.66±10.21*</td>
<td>69.21±9.77*</td>
<td>265.32±44.82*</td>
</tr>
</tbody>
</table>

Attention: *compared with control group, P<0.05.
temporary headache or dizziness, but no other severe side effects. However, overdose treatment can cause adverse reactions in the central nervous system, digestive system and blood system of patients and even leads to drowsiness, dizziness, fatigue, abdominal pain, heart palpitations and ECG abnormalities and other symptoms [17].

Desloratadine citrate disodium is a first anti allergy medicine invented by Chinese, and it’s the only ideal drug fully meets the requirements of antihistamines currently. The pharmacological effects of desloratadine citrate is inhibit H1 receptor and mast cells releasing histamine and other allergic substances by selective competition, it can effectively inhibit inflammatory medium releasing in multiple taches during the early stage and advanced stage of inflammation, and has certain effect on IgE level control. Compared with desloratadine, it has advantages of faster onset, better therapeutic effect, higher stability and smaller side effects, Desloratadine citrate disodium have better anti-inflammatory potential by comparing with the similar drugs of cetirizine hydrochloride and ebstine. The function features of desloratadine citrate disodium mainly are: 1. Strong anti-allergic effects: desloratadine citrate disodium combined H1 receptor specifically with high selectivity. In the currently known antihistamines, desloratadine citrate disodium has the strongest combination capability with H1 receptor, possessing significant function of H1 receptor antagonist. It’s 4 times stronger than loratadine in the inhibition of mice nose swelling induced by histamine. Desloratadine citrate disodium inhibits inflammatory cytokines from stimulated human mast cells and eosinophils at nanomolar levels, the cytokines includes IL-3, IL-6, TNF, GM-CSF, etc. The effect is stronger than dexamethasone and cetirizine levocetirizine. 2. Rapid onset, sustained efficacy: desloratadine citrate has water solubility, good absorption, and the onset time is less than 30 minutes. Researching reports show that [19], desloratadine citrate disodium is faster than the existing antihistamine drug in onset time, the average of which is 28.45 minutes, while 1 hour for loratadine and mizolastine, 2 hours for cetirizine. Half life time of desloratadine citrate disodium is about 24 hours that sustained effect. After oral feeding, desloratadine is rejected by the central nervous system effect-}

tively; therefore it can antagonize peripheral H1 receptor selectively. In addition to the antihistamine function, desloratadine also reveals anti-allergic and anti-inflammatory effects, and shows inhibitory effect on many taches during early and advanced periods of allergic inflammation in vitro experiments. Including: the release of inflammatory cytokines (IL-4, IL-6 and IL-8 and IL-13), important chemokines in inflammation, such as RANTES (activity regulation factor expressed and secreted by normal T cell); Reactive oxygen species generated by activating polymorphic neutrophilic cells; adhesion and chemotactic activity of eosinophilic granulocyte; the expression of adhesion molecules like P-selectin; IgE-dependent release of PGD2 and LTC4. Animal experiments have confirmed that desloratadine citrate disodium can relieve nasal itching and runny nose symptoms significantly, reducing the expression of IL-4 to suppress the inflammatory response of the nasal mucosa by reducing the concentration of serum levels of IFN-γ and IL-12. Desloratadine citrate disodium can reduce AR symptoms by regulating reaction of T cell, which is increasing the level of Th1 cell and inhibiting the level of Th2 cells [20].

In this study, the total effective rate of the observation group was 92.9%, the control group was 76.5%, while the observation group having 7 (7%) adverse reaction cases and the control group having 15 cases (15%), which were nausea, headache, dizziness, fatigue, sleepiness and skin rash, etc. Obviously, compared with loratadine, desloratadine can improve the treatment efficiency and reduce the incidence of adverse reactions of AR patients (P<0.05). To discuss the differences in the anti allergic effects between desloratadine citrate disodium and loratadine, this study constructed sensitized mouse model by intraperitoneal injection of ovalbumin (OVA) and aluminum hydroxide, separated and cultured mice spleen lymphocytes; We detected the influence of desloratadine citrate disodium on lymphocyte releasing PGE2, LTB4, IL-4, IL-5, and TNF-α such inflammation related factors, and compared with loratadine. The experimental results indicated that desloratadine citrate disodium can reduce the level of PGE2, LTB4, IL-4, IL-5, and TNF-α significantly and possess early anti-inflammatory potential. So, it provided an important experimental basis to demonstrate and
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In summary, desloratadine citrate disodium treats AR by reducing the level of PGE$_2$, LTB$_4$, IL-4, IL-5, and TNF-α, it can relieve the symptoms and signs of runny nose, nasal congestion, sneezing, nasal itching and inferior turbinate swelling of patients. The clinical curative effect is better than loratadine, and has good safety and strong anti-inflammatory effect. It is also the only one in the full compliance with the requirements of the antihistamine medicine; with faster onset, better efficacy, less side effects, it is worthy of wide clinical application.

Disclosure of conflict of interest

None.

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References


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