Effect of Tongqiao Biyan granule in combined with montelukast sodium and budesonide on of allergic rhinitis and inflammatory cytokines

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ABSTRACT

Objective: To explore the clinical efficacy of Tongqiao Biyan granule in combined with montelukast sodium and budesonide in the treatment of allergic rhinitis (AR) and their effects on IL-6, IL-8, and IL-10. Methods: A total of 50 patients with AR who were admitted in our hospital from October, 2014 to October, 2015 were included in the study and randomized into the observation group and the control group. The patients in the control group were orally given montelukast sodium, 10 mg/time, 1 time/d, and budesonide spray, 64 μg/time, 2 times/d for nasal spray. On this basis, the patients in the observation group were given Tongqiao Biyan granules, 2 g/time, 3 times/d. A continuous 3-week treatment was given in the two groups. The clinical symptom scores, the clinical therapeutic effect, and the effect on serum IL-6, IL-8, and IL-10 before and after treatment in the two groups were observed and compared. Results: After treatment, the symptom scores of sneeze, stuffy nose, rhinocnesmus, and running nose in the two groups were reduced, and the reduced degree in the observation group was significantly superior to that in the control group (P<0.05). The total effective rate in the observation group (96.0%) was significantly superior to that in the control group (80.0%) (P<0.05). After treatment, the levels of IL-6 and IL-8 in the two groups were elevated, while IL-10 level was reduced, and those in the observation group were significantly superior to those in the control group (P<0.05). Conclusions: Tongqiao Biyan granule in combined with montelukast sodium and budesonide in the treatment of AR can effectively alleviate the inflammatory reaction, and significantly improve the clinical symptoms with a reliable efficacy; therefore, it deserves to be widely recommended in the clinic.

1. Introduction

Allergic rhinitis (AR) is a chronic inflammatory reactive disease of nasal mucosa mediated by IgE under the combined involvement of various inflammatory cells and cytokines after exposure to the allergens, with clinical manifestations of paroxysmal sneeze, clear watering nasal discharge, rhinocnesmus, eye itching, and obstructive sleep-disordered breathing in severe patients, and is characterized by long course, repeated attack, and delayed healing, which can seriously affect the patients’ living qualities[1,2]. It is found during studying the pathogenesis of AR that the inflammatory reaction is involved in the genesis and development of AR, and interleukin plays an important promoting role[3]. Drugs are mainly involved in the treatment of AR, among which the anti-histamine drugs and glucocorticoids are the main core drugs, but the occurrence rate and side effects are relatively high, while the traditional Chinese medicine has an unique advantage[4]. The study is aimed to explore the clinical efficacy of Tongqiao Biyan granule in combined with montelukast sodium and budesonide in the treatment of AR and their effects on IL-6, IL-8, and IL-10.

2. Materials and methods

2.1. General materials

A total of 50 patients with AR who were admitted in our hospital...
from October, 2014 to October, 2015 were included in the study and randomized into the observation group and the control group. All the patients were in accordance with the diagnostic criteria of AR in the diagnostic principle and recommended proposal of AR[5]. In the observation group, there were 25 cases, 13 were male, and 12 were female; aged from 21 to 48 years old with an average age of (34.2±3.5) years old; course from 0.5 to 10 years with an average course of (4.8±1.2) years. In the control group, there were 25 cases, 14 were male, and 11 were female; aged from 21 to 48 years old with an average age of (35.1±3.4) years old; course from 0.5 to 10 years with an average course of (4.7±1.6) years. The comparison of the general materials between the two groups was not statistically significant (P>0.05).

2.2. Inclusion and exclusion criteria

Inclusion criteria: (1) those who were in accordance with the diagnostic criteria of AR[5]; (2) those whose IgE level was elevated; (3) those who had not taken anti-histamine drugs and hormones in recent one month; (4) those who volunteered to receive the treatment. Exclusion criteria: (1) those who had medical histories of nasal polyp, deviated nasal septum, and purulent sinusitis; (2) those who were merged with asthma, cardiovascular and cerebrovascular diseases, and severe liver and kidney disease; (3) those who were pregnant and during the lactation period.

2.3. Methods

The patients in the control group were orally given montelukast sodium, 10 mg/time, 1 time/d, and budesonide spray, 64 μg/time, 2 times/d for nasal spray. On this basis, the patients in the observation group were given Tongqiao Biyan granules (produced by Dikang Scientific and Technological Pharmaceuticals of Sichuan Province, Approval No. Z10980073), 2 g/time, 3 times/d. A continuous 3-week treatment was given in the two groups. No other related drugs were taken during the medication period. Exposure to the allergens was avoided.

2.4. Observation indicators

The clinical symptom scores before and after treatment in the two groups were observed and compared. 1 score: a continuous 4–6 sneeze each time, blowing nose 4 times/d, intermittent occurrence of rhinocnesmus, feeling stuffy nose when inhaling on purpose; 2 scores: a continuous 6–10 sneeze each time, blowing nose 5–9 times/d, intermittent or interactive occurrence of stuffy nose, ant line feeling rhinocnesmus, but could endure; 3 scores: a continuous 11 sneeze each time, blowing nose 10 times/d, severe stuffy nose, breathing with mouth nearly in a whole day, ant line feeling rhinocnesmus, and could endure. The efficacy was evaluated according to the diagnosis and treatment guideline of AR[5]. Cured: clinical manifestations completely disappearing, no recurrence after half a year follow-up visit; effective: symptoms disappearing, signs significantly improved, occasional recurrence; invalid: no improvement or aggravation of clinical manifestations. The morning fasting elbow venous blood was taken before and after treatment, and centrifuged for serum. ELISA was used to detect the serum IL-6, IL-8, and IL-10 levels. The kits were provided by Shanghai Hengyuan Biotech Company.

2.5. Statistical analysis

SPSS 18.0 software was used for the statistical analysis. The measurement data were expressed as mean±SD, and t test was used. The enumeration data were expressed as percentage, and Chi-square test was used. P<0.05 was regarded as statistically significant difference.

3. Results

3.1. Symptom scores before and after treatment

The differences in symptom scores of sneeze, stuffy nose, rhinocnesmus, and running nose before treatment between the two groups were not statistically significant (P>0.05). After treatment, the scores of various indicators in the two groups were reduced, and the reduced degree in the observation group was significantly superior to that in the control group (P<0.05) (Table 1).

3.2. Clinical efficacy

In the observation group, after treatment, 15 (60.0%) were cured, 9 (36.0%) were effective, 1 (4.0%) were invalid, and the total effective rate was 96.0%. In the control group, after treatment, 9 (36.0%) were cured, 11 (44.0%) were effective, 5 (20.0%) were invalid, and the total effective rate was 80.0%. The total effective rate in the observation group was significantly higher than that in the control group (P<0.05).

Table 1

<table>
<thead>
<tr>
<th>Groups</th>
<th>Time</th>
<th>Sneeze</th>
<th>Stuffy nose</th>
<th>Rhinocnesmus</th>
<th>Running nose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation group</td>
<td>Before treatment</td>
<td>2.58±0.57</td>
<td>2.61±0.36</td>
<td>2.60±0.32</td>
<td>2.55±0.37</td>
</tr>
<tr>
<td></td>
<td>After treatment</td>
<td>0.65±0.21</td>
<td>0.88±0.25</td>
<td>0.86±0.21</td>
<td>0.78±0.17</td>
</tr>
<tr>
<td>Control group</td>
<td>Before treatment</td>
<td>2.55±0.68</td>
<td>2.57±0.45</td>
<td>2.61±0.32</td>
<td>2.54±0.45</td>
</tr>
<tr>
<td></td>
<td>After treatment</td>
<td>1.58±0.31</td>
<td>1.46±0.23</td>
<td>1.56±0.30</td>
<td>1.35±0.22</td>
</tr>
</tbody>
</table>

*P<0.05, when compared with before treatment; *P<0.05, when compared with the control group.
3.3. Serum IL-6, IL-8, and IL-10 levels before and after treatment

The comparison of the serum IL-6, IL-8, and IL-10 levels before treatment between the two groups was not statistically significant ($P>0.05$). After treatment, the levels of IL-6 and IL-8 in the two groups were elevated, while IL-10 level was reduced, and those in the observation group were significantly superior to those in the control group ($P<0.05$) (Table 2).

<table>
<thead>
<tr>
<th>Groups</th>
<th>n</th>
<th>Time</th>
<th>IL-6</th>
<th>IL-8</th>
<th>IL-10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observation group</td>
<td>25</td>
<td>Before treatment</td>
<td>198.57±17.25</td>
<td>176.25±16.61</td>
<td>10.51±3.11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>After treatment</td>
<td>102.71±10.61*</td>
<td>110.15±11.74*</td>
<td>18.14±3.15*</td>
</tr>
<tr>
<td>Control group</td>
<td>25</td>
<td>Before treatment</td>
<td>196.28±15.34</td>
<td>176.20±14.56</td>
<td>10.38±3.71</td>
</tr>
<tr>
<td></td>
<td></td>
<td>After treatment</td>
<td>143.42±11.21*</td>
<td>139.72±10.57*</td>
<td>12.12±4.43*</td>
</tr>
</tbody>
</table>

*P<0.05, when compared with before treatment; *P<0.05, when compared with the control group.

4. Discussion

AR is a common disease of ENT, belonging to the chronic allergic reaction disease, and is a type I allergic reaction mediated by IgE, with complex pathogenesis and many cytokines and inflammatory mediators involved, whose immunological basis is the imbalance of immunoreaction between Th1 and Th2[6]. The anti-histamine drugs and glucocorticoids, the first choices for the treatment of AR, can effectively reduce the release of cytokines in the nasal mucous and the infiltration of inflammatory cells, and effectively inhibit the production of inflammatory mediators, but their side effects are large with an undesirable long-effect and easy recurrence[7]. With the development of medicine, the traditional Chinese medicine is widely applied in the clinic in that it can control the progression of AR, regulate the body, effectively adjust the cytokine level, reduce IgE mediation, and alleviate the clinical symptoms with a stable efficacy and less side effects[8].

Cytokine imbalance exists in AR patients, manifesting in the hyperfunction of Th2 cell. It is reported that regulation of the imbalance of Th1/Th2, expression levels of cytokines, and IgE level in AR patients can significantly improve the clinical symptoms[9]. The pathogenesis of AR is associated with the abnormal expression of cytokines. The abnormal expression of inflammatory cytokines plays a crucial role in the attack of AR. The proliferation, differentiation, and performing function of immune cells are closely associated with the cytokines, which possess an important immunoregulation function. Interleukin, as an important inflammatory cytokine, is involved in the regulation of immune system[10,11]. IL-6 is mainly produced by T helper cells and mononuclear macrophages, is the cytokine produced by various cell reaction, and can increase the synthesis and secretion of IgE, activate and promote the neutrophils aggregated in the inflammatory sites, delay the cell apoptosis, release the oxygen radicals, mediate the humoral immunity, and is involved in the inflammatory reaction[12]. IL-8 is mainly produced by the mononuclear-macrophages and neutrophils, is an important determining factor in the respiratory injury mediated by the neutrophils, and can promote and activate the inflammatory cells aggregated in the airway mucosa, induce the neutrophils to release the proteolytic enzyme, inhibit the neutrophil apoptosis, and act on the specific receptors on the target cells to trigger an inflammation or allergic reaction, thus leading to the nasal mucosal injury and aggravating the inflammatory reaction[13]. IL-10 is produced by Th2 cells, monocytes, and macrophages, is a multifunctional negative regulatory factor, is involved in the regulation of inflammatory cells and immune cells, is a kind of anti-inflammation cytokine, and can inhibit the formation of neutrophils, down-regulate the inflammatory reaction, and antagonize the inflammatory mediator[14].

Montelukast sodium belongs to leukotriene receptor antagonist, is combined with CysLTs receptor, block the leukotriene pathway during the process of inflammation occurrence, and inhibit the inflammatory reaction caused by allergens so that to relieve the clinical symptoms. Moreover, leukotriene can alleviate the infiltration of local inflammatory cells in the airway tract, and relieve the hyper-responsiveness in order to reach the goal of treating AR[15]. Budesonide belongs to the steroid drugs, and can act on the nasal mucous to play a role in anti-allergic reaction and inflammation, and affect the synthesis and release of inflammatory mediators in order to reaching the goal of alleviating the symptoms of AR[16]. AR belongs to the scope of Biqiu, and the key treatment lies in yang raising and orifice-opening, spleen and lung tonifying. Tongqiao Biyan granule is composed of astragalus, atractylodes, *Radix saposhnikoviae*, *Asarum sieboldii*, and *Siberian cocklour* fruit, possesses the effects of heating clearing and orifice-opening, and pain relieving and turbidity dissolving, can effectively reduce the nasal mucosal edema and secretions, and alleviate the clinical symptoms[17]. The modern pharmacological researches demonstrate that astragalus possesses a bi-directional immune regulation effect and can enhance the body immunity; atractylodes can dispel wind to relieve exogenous syndrome, regulate T lymphocyte function, up-regulate IL-2 and cytokines in Th channel, strengthen the phagocytosis of RES, enhance the adaptability of lymphocytes, inhibit the allergic
reaction, and reduce the nasal mucosal tissue edema; *Radix saposhnikoviae* can effectively reduce the permeability of cytokines, alleviate the nasal mucosal edema, and posses a preferable anti-inflammation effect [18,19]. The results in the study showed that after treatment, the symptom scores of sneeze, stuffy nose, rhinosinusitis, and running nose in the two groups were reduced, and the reduced degree in the observation group was significantly superior to that in the control group (P<0.05); the total effective rate in the observation group (96.0%) was significantly superior to that in the control group (80.0%) (P<0.05); after treatment, the levels of IL-6 and IL-8 in the two groups were elevated, while IL-10 level was reduced, and those in the observation group were significantly superior to those in the control group (P<0.05), indicating that the application of combined drugs can effectively reduce the nasal mucosal inflammatory reaction and eliminate the clinical symptoms.

In conclusion, Tongqiao Biyan granule in combined with montelukast sodium and budesonide in the treatment of AR can effectively alleviate the inflammatory reaction, and significantly improve the clinical symptoms with a reliable efficacy; therefore, it deserves to be widely recommended in the clinic.

References


