

Desloratadine citrate combined with compound glycyrrhizin in the treatment of subacute eczema: A randomized trial

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Abstract: To investigate the efficacy of desloratadine citrate combined with compound glycyrrhizin in the treatment of subacute eczema. 100 patients with subacute eczema who were admitted in our hospital from June 2019 to June 2020 were selected according to the order of admission, and divided into experimental groups (n=50, using a single compound glycyrrhizin) and control group (n=50, using compound glycyrrhizin combined with desloratadine citrate); the curative effect was compared between the two groups. After treatment, the inflammatory factors in the experimental group were lower than those in the control group [TNF- α (ng/L) (35.16 \pm 3.31), IL-2 (pg/ml) (24.39 \pm 3.11), IL-4 (pg/ml) (39.82 \pm 4.48) vs TNF- α (ng/L) (44.24 \pm 3.87), IL-2 (pg/ml) (41.68 \pm 3.89), IL-4 (pg/ml) (49.88 \pm 5.74)] (P <0.05). After treatment the adverse reaction rate of the experimental group was lower than that of the control group (P <0.05). After treatment, the experimental group yielded higher total effective rate in relative to the control group (P <0.05). Desloratadine citrate plus compound glycyrrhizin for might be a preferable option for clinical treatment of patients with subacute eczema, with an ideal effectiveness profile.

Keywords: Desloratadine citrate, compound glycyrrhizin, subacute eczema.

INTRODUCTION

Eczema, a common skin allergic disease, can be classified as acute, subacute and chronic stages. Among them, subacute eczema witnesses a higher prevalence with the skin lesions of scale or crusting-like (Fernandez-Sartorio *et al.*, 2019; Li *et al.*, 2021; Ma T. *et al.*, 2020). The major presentations are itching symptoms, and the course of the disease is rather long, which predisposes to recurrence and undermines the physical and mental health of the patient (Andersson *et al.*, 2020) (Fritz *et al.*, 2020). Since the exact pathophysiological mechanism of eczema has not been fully elucidated, there is no optimal cure. Western medicine usually uses glucocorticoids, antibacterial drugs, immunomodulators, and other drugs to treat eczema. However, high recurrence rates, side effects, and drug resistance are a constant concern. Therefore, it is necessary to develop alternative effective agents with few side effects. In light of this, the present study was undertaken to explore the efficacy of desloratadine citrate combined with compound glycyrrhizin in the clinical treatment of patients with subacute eczema.

MATERIALS AND METHODS

General data

One hundred patients with subacute eczema admitted to our hospital from June 2019 to June 2020 were selected and divided into experimental group (n=50) and control group (n=50) according to the order of admission. In the

experimental group, there were 27 cases of male, 23 females; aged 17-63 years old, with an average age of (34.72 \pm 3.85) years old; disease course 1-17 months, with an average disease course of (6.27 \pm 1.48) months. In the control group, there were 25 males and 25 females; aged 15-62 years, with an average age (34.11 \pm 3.27) years old; disease course 1-16 months, with an average disease course (6.82 \pm 1.17) months. All patients in this study were informed and participated voluntarily. The baseline data of the two groups were of comparability (P >0.05).

Inclusion and exclusion criteria

Inclusion criteria: patients with subacute eczema; patients with no history of drug allergy; patients with first onset; patients with good compliance; patients with clear consciousness.

Exclusion criteria

Pregnant or lactating women; those who cannot cooperate with the study; patients who have recently received antihistamine therapy; patients with tumors or liver and kidney diseases.

Treatment methods

The control group used compound glycyrrhizin alone at a dosage of 50 mg/time in the morning, at noon and at night. The experimental group was treated with compound glycyrrhizin + desloratadine citrate the dosage of desloratadine citrate was 8.8mg/time and it was administered once a day. A course spanned 7 days, for a total three courses in the two groups. During the treatment, the patient should be on a light diet, ensure sufficient rest; the skin damage should be closely observed during the

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treatment, and anti-inflammatory treatment is provided if necessary (Ahmad *et al.*, 2021; Cho *et al.*, 2021; Khan *et al.*, 2021; Liang *et al.*, 2022).

Observation indicators

Treatment efficacy. Markedly effective is considered if the patient's skin condition is restored, the clinical symptoms disappear, and no recurrence occurs within a short period of time after drug withdrawal; effective is considered if the patient's skin condition is immensely restored, and the clinical symptoms have improved and no recurrence occurs within a short period of time after drug withdrawal; ineffective is considered if the patient's skin condition and clinical symptoms are not improved or even worsen. Total effectiveness was calculated as follows: $TTE = (CC + ME + E) / TNC \times 100\%$, where TTE = Total treatment effectiveness, CC = Clinically controlled, ME = markedly effective, E = effective and TNC = Total number of cases.

Inflammatory factors. TNF- α , IL-2, IL-4 were determined before and after treatment. Complications. The complications such as dry mouth, fatigue, dizziness, headache and drowsiness were recorded and compared.

Ethical approval

This study was reviewed and approved by the ethic committee of Anqing First People's Hospital Affiliated to Anhui Medical University, with the approval no. AQ20190230. The study was conducted in accordance with the protocols of Declaration of Helsinki.

STATISTICAL ANALYSIS

The data analysis was done by SPSS22.0. The measurement data such as inflammatory factors were expressed as ($\bar{x} \pm s$), and the independent sample T test was used for the comparison; the count data such as complications and total effectiveness rate were expressed as the number of cases (rate), and the chi-square test was used for the comparison. $P < 0.05$ indicated a statistically significant difference.

RESULTS

General information of the patient

The two groups were not statistically different in gender, age, and course of disease ($P > 0.05$, table 1).

Comparison of inflammatory factors between the two groups of patients

After treatment, the inflammatory factors in the experimental group were lower than those in the control group [TNF- α (ng/L) (35.16 ± 3.31), IL-2 (pg/ml) (24.39 ± 3.11), IL-4 (pg/ml) (39.82 ± 4.48) vs TNF- α (ng/L) (44.24 ± 3.87), IL-2 (pg/ml) (41.68 ± 3.89), IL-4 (pg/ml) (49.88 ± 5.74)] ($P < 0.05$). See table 2.

Comparison of complications between the two groups

After treatment, there were 2(4%) cases of dry mouth, 4(8%) cases of fatigue, 2(4%) cases of dizziness and headache and 6(12%) cases of drowsiness, with total incidence of 14(28%) in the control group; while there were 1(2%) cases of dry mouth, 1(2%) cases of fatigue, 0(0%) cases of dizziness and headache and 3 (6%) cases of drowsiness, with the total incidence of 5 (10%). Overall, the adverse reaction rate of the experimental group was lower than that of the control group ($P < 0.05$). See table 3.

Comparison of the total effective rate of treatment between the two groups of patients

After treatment, 17 (34%) cases were markedly effective in the control group, 22 (44%) cases were effective, 11 (22%) cases were ineffective, and the total effective rate was 78%. In the experimental group, 28 (56%) cases were markedly effective, 19 (38%) cases were effective and 2(4%) cases were ineffective, and the total effective rate was 94%. The experimental group yielded higher total effective rate in relative to the control group ($P < 0.05$, table 4).

DISCUSSION

Eczema, a skin allergic disease, witnesses a high incidence. The clinical manifestations are skin damage accompanied by hyperplasia of dander, pruritus, etc. and the recurrence rate is rather high, serving as a challenging issue. Subacute eczema, a common stage of eczema, is considered to be intermediate between chronic eczema and acute eczema. It is more likely to worsen without proper treatment, leading to prolonged disease and unhealing and further compromising the physical and mental health of patients. Currently, the mainstay for this disease is corticosteroids, antihistamines and other related drugs. Unfortunately, patients are prone to drug resistance over time, and they are susceptible to disease recurrence once the drug is discontinued, emanating an undesirable efficacy. Previous studies reported a promising outcome of desloratadine citrate and compound glycyrrhizin in the clinical treatment of patients with subacute eczema.

In this study, the experimental group observed a higher effective rate of treatment and lower inflammatory factors (TNF- α , IL-2 and IL-4). Encouragingly, the adverse reaction rate of patients in the experimental group was also lower. The reasons might be attributive to the followings. First, compound glycyrrhizin, a commonly used drug for the treatment of subacute eczema (Tan *et al.*, 2021), has similar activity and structure to corticotropin and its main components are glycine, glycyrrhizin and cysteine hydrochloride, which have roles in inhibition of inflammation spread, immune regulation; its long-lasting anti-allergic effect can relieve congestion, improve capillary permeability, play a role in inhibiting

Table 1: Comparison of general data of the two groups of patients (n %)

| | Experimental group (n=50) | Control group (n=50) | t or X ² | P |
|--------------------------------|---------------------------|----------------------|---------------------|-------|
| Gender | | | 0.16 | 0.689 |
| Male | 27 | 25 | | |
| Female | 23 | 25 | | |
| Mean age (year) | 34.72±3.85 | 34.11±3.27 | 0.14 | 0.889 |
| Average disease course (month) | 6.27±1.48 | 6.82±1.17 | 1.124 | 0.264 |

Table 2: Comparison of inflammatory factors between the two groups (x ± s)

| Groups | N | TNF- α (ng/L) | | IL-2 (pg/ml) | | IL-4(pg/ml) | |
|--------------------|----|----------------------|-------------------------|------------------|-------------------------|------------------|-------------------------|
| | | Before treatment | After treatment | Before treatment | After treatment | Before treatment | After treatment |
| Control group | 50 | 54.31±5.78 | 44.24±3.87 | 62.78±8.87 | 41.68±3.89 | 80.14±11.98 | 49.88±5.74 |
| Experimental group | 50 | 55.14±5.32 | 38.16±3.31 ^a | 62.34±8.65 | 26.39±3.11 ^a | 80.37±11.64 | 40.82±4.48 ^a |
| t | - | -0.747 | 12.608 | 0.251 | 24.548 | -0.097 | 9.769 |
| p | - | 0.457 | 0.0212 | 0.802 | 0.0362 | 0.923 | 0.002 |

Note: a represents that the values after treatment was statistically different from the corresponding values before treatment.

Table 3: Comparison of complications between the two groups (n %)

| Groups | N | Dry mouth | Fatigue | Dizziness and headache | drowsiness | total |
|--------------------|----|-----------|---------|------------------------|------------|---------|
| Control group | 50 | 2 (4%) | 4(8%) | 2(4%) | 6(12%) | 14(28%) |
| Experimental group | 50 | 1(2%) | 1(2%) | 0(0%) | 3(6%) | 5(10%) |
| X ² | - | - | - | - | - | 5.263 |
| P | - | - | - | - | - | 0.022 |

Table 4: Comparison of the total effective rate of treatment between the two groups of patients (n %)

| Groups | N | Markedly effective | Effective | Ineffective | Total |
|--------------------|----|--------------------|-----------|-------------|---------|
| Control group | 50 | 17(34%) | 22(44%) | 11(22%) | 39(78%) |
| Experimental group | 50 | 28(56%) | 19(38%) | 3(6%) | 47(94%) |
| X ² | - | - | - | - | 5.316 |
| P | - | - | - | - | 0.021 |

complement in the body, antibody production and then the release of carnosine or histamine from mast cells.

In addition, glycyrrhizin also plays a sedative and hypnotic role, relieves patients' irritability and is thereby conducive to disease recovery (Wang H *et al.*, 2021; Wang HN *et al.*, 2021). However, prior studies reported a negative impact of long-term or large amounts of compound glycyrrhizin such as edema, elevated blood pressure, hypokalemia, etc. As a consequence, adverse responses such as poor compliance and recurrence after drug withdrawal arise, causing a somber efficacy (Kusano *et al.*, 2021; Ma J. *et al.*, 2020; Yonekura *et al.*, 2019; Zhang and Li, 2020; Zhang *et al.*, 2020a). Desloratadine citrate, a non-sedating long-acting tricyclic antihistamine drug, is an active metabolite of loratadine and a new generation of H1 receptor antagonist with a favorable selectivity for peripheral H1 receptors. Importantly, it can inhibit inflammatory factors, reduce their expression activity, increase anti-inflammatory and inhibit histamine effects on the basis of antagonizing H1 receptors and then

more effectively control eczema symptoms and mitigate patients inflammatory response. Excitingly, the drug features fast action, long half-life and long duration of action, etc., with higher safety profile (Meng *et al.*, 2021; Navarro-Trivino and Ruiz-Villaverde, 2020; Peters and Peters, 2019; Zhang *et al.*, 2020b).

CONCLUSION

Collectively, desloratadine citrate plus compound glycyrrhizin for might be a preferable option for clinical treatment of patients with subacute eczema, with an ideal effectiveness profile.

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