CLINICAL EFFICACY OF TRIAMCINOLONE ACETONIDE ACUPOINT INJECTION COMBINED WITH COMPOUND KUGAN MIXTURE ON ANAL ECZEMA AND ITS EFFECT ON SERUM IL-2, IL-4, IL-6, AND GAS

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ABSTRACT

Objective: To investigate the clinical efficacy of triamcinolone acetonide acupoint injection combined with compound Kugan mixture in the treatment of anal eczema and the effect on serum IL-2, IL-4, IL-6, and Gas.

Method: A total of 122 patients with anal eczema who were admitted to the dermatological department of our hospital from January 2011 to June 2014 were selected and randomly divided into two groups: a treatment group (n = 61) and a control group (n = 61). Patients in the control group were treated with mormisone furoate cream following a hip bath with warm water. Patients in the treatment group were given triamcinolone acetonide acupoint injections combined with a compound Kugan mixture fumigation treatment. Both groups were treated continuously for 1 month, and the clinical curative effect of the two groups was observed. The levels of serum IL-2, IL-4, IL-6, and Gas was evaluated alongside the lesion area score. Clinical syndrome score changes for Traditional Chinese Medicine (TCM) (pruritus, exudation, burning, rash, upset, thirsty, yellow urine, and dry stool) were also compared before and after treatment. The occurrence of adverse reactions in the two groups was also observed.

Results: The total effective rate of the treatment group was 95.08%, which was significantly higher than that of the control group (83.61%), with a significant difference observed between the two groups (P<0.05). After treatment, the clinical syndrome and skin lesion area scores in the two groups were significantly lower than those before treatment, with a significant difference between the two groups (P<0.05). The levels of serum IL-2 in the two groups were significantly higher than those before treatment, while levels of IL-4, IL-6, and Gas were significantly lower. Changes in the treatment group were more obvious and statistically significant (P<0.05). There was no significant difference in the incidence of adverse reactions in the two groups (P > 0.05). The incidence of adverse reactions was 5.28% in the control group and 2.64% in the treatment group, and no significant difference was observed between the two groups (P>0.05).

Conclusion: The curative efficacy of triamcinolone acetonide acupoint injection combined with compound Kugan mixture on the treatment of anal eczema is evident. Moreover, the tolerance is good, and the purpose of treating the perianal eczema of the patient can be achieved by improving the serum IL-2, IL-4, IL-6, and Gas levels.

Keywords: Triamcinolone acetonide acupoint injection, compound Kugan mixture, perianal eczema, IL-2, IL-4, IL-6, gas.

DOI: 10.19193/0393-6384_2019_4_288

Received November 30, 2018; Accepted February 20, 2019

Introduction

Anal eczema, namely perianal eczema, is a type of perianal skin exudative inflammatory allergic reaction caused by a variety of factors. This reaction is primarily manifested as perianal skin pruritus and a repeated course of disease, among other conditions, with erythema, papules, and chapping appearing on perianal skin. Due to the dense distribution of various nerves around the anus, it is very sensitive sensations such as itching and pain, which can seriously affect patients’ quality of life. Anal eczema has brought a lot of inconvenience and pain to individuals, and the treatment method of many Western medicines, such as corticosteroids, has obtained immediate effects; however, the side effects are large and the recurrence rate is high. In TCM, damp heat is regarded as the main pathogenesis of the disease, and combined treatment with TCM and western medicine has a significant curative effect. In the present study, triamcinolone acetonide acupoint injection combined with an external application of compound Kugan mixture are used to explore the application value of triamcinolone acetonide in the treatment of anal eczema.
Data and methods

General information
A total of 122 patients with anal eczema who were admitted to the Dermatological Department of our hospital between January 2011 and June 2014 were selected and randomly divided into two groups: a treatment group (n=61) and a control group (n=61) using the random number table method. Inclusion criteria: According to the criteria for diagnosis and treatment of the syndrome using TCM, patients were selected in accordance with the diagnostic criteria of anal eczema; perianal skin itching with an erosive lesion; patients with a clear mind that can consciously follow the doctor’s medication orders and maintain regular visits. With hospital ethics approval, all patients or their families agreed to participate in the study and signed an informed consent form. Exclusion criteria: Patients had taken antihistamines or corticosteroids within one week; patients with severe cardiac insufficiency; patients in lactation or presenting with other anal diseases such as haemorrhoids. There were 31 male patients and 30 female patients in the treatment group, aged 20 to 55 years old, with the average age of 38.32±3.67 years old. The course of the disease ranged from 3 months to 2 years, with a mean course of 1.31±0.11 years. In the control group, there were 32 males and 29 females, aged 22 to 59 years old, with an average age of 41.21±2.93 years old. The course of disease in this group ranged from 3 months to 2 years, with a mean course of 1.29±0.29 years. As shown in Table 1, there was no significant difference in age, sex, or course of disease between the two groups (P>0.05).

<table>
<thead>
<tr>
<th>Groups</th>
<th>n (cases)</th>
<th>Age (years old)</th>
<th>Course of disease (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment group</td>
<td>31 Male</td>
<td>38.32±3.67</td>
<td>1.31±0.11</td>
</tr>
<tr>
<td></td>
<td>30 Female</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control group</td>
<td>32 Male</td>
<td>41.21±2.93</td>
<td>1.29±0.29</td>
</tr>
<tr>
<td></td>
<td>29 Female</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table. 1: Comparison of age, sex, and course of disease between the two groups.

Therapeutic method
Patients in the control group were treated with mormisone furoate cream (Zhejiang Xianju Pharmaceutical Co., Ltd., specifications: 10mg, 10g) following a hip bath with warm water. A proper amount of medicine was applied to the affected area once per day. Patients in the treatment group were given compound triamcinolone acetonide solution (Shanghai Xinya Pharmaceutical Minhang Co., Ltd., Specification: 10mL) combined with compound Kugan mixture (Radix sophorae flavescentis 25g, liquorice 30g, rhubarb, alum, and Radix saposhnikoviae 10 g each, Herba lycopii, Phellodendron, and Fructus cnidii 15 g each, Poria cocos, bighead Atractyloides rhizome, Rhizoma atractyloids, and tangerine peel 20 g each) as an external application treatment. The patients were in the position of supine knee flexion to wash the skin and routinely disinfect. After injection of the needle on both sides of the Quchi point, no blood was drawn back, and 1mL of triamcinolone acetonide was injected into each side. The Radix sophorae flavescentis, rhubarb, alum, Radix saposhnikoviae, and other medicinal materials were soaked in 1000 to 1500 mL water for boiling and taking the decoction. During treatment, the affected skin was cleaned and the decoction was placed under the anus for fumigation. Sterile gauze was immersed in the liquid, and, after soaking, the gauze was wrung out to not drip water, and then applied to the affected area around the anus as a wet compress. The treatment was performed twice per day, with each treatment lasting for 30 minutes. Both groups were treated continuously for 1 month, excluding treatment that might affect the outcome, such as oral antihistamine. Changes in serum interleukin-2 (IL-2), interleukin-4 (IL-4), interleukin-6 (IL-6), and gastric gastrin (Gas) were recorded before and after treatment.

A total of 5mL fasting venous blood was extracted from patients in both groups in the morning before and after treatment, and serum was taken after centrifugation. Changes in serum IL-2, IL-4, IL-6, and Gas levels were observed by enzyme-linked immunosorbent assay (ELISA) before and after treatment in the two groups. Efficacy criteria: the evaluation was carried out according to the relevant contents in the Standard for the Diagnosis and Treatment of the Diseases of the Traditional Chinese Medicine (TCM). Cure: The degree of symptom abatement reached more than 90% of the total score of skin lesion area diameter and pruritus degree. Obvious effect: the degree of symptom abatement reached 60% to 90% of the total score; Effective: The degree of symptom abatement reached 30% to 60% of the total score. Ineffective: symptoms abatement less than 30%. Adverse reactions: The occurrence of adverse reactions in both groups during treatment was monitored. Changes in skin lesion area score and clinical symptom score were recorded before and after treatment.
Statistical method
The results of the study were statistically analysed using SPSS17.0 software. The $\chi^2$ test was used to compare the counting data, an independent sample t-test was used to analyse the measurement data, and a Ridit test was used to compare the grade data. $P<0.05$ indicates that statistical results were statistically significant, while and $P>0.05$ indicates no statistical significance.

Results

Comparison of clinical efficacy
The total effective rate was 95.08% in the treatment group and 83.61% in the control group, and was significantly higher in the treatment group than in the control group ($P<0.05$). The results are presented in Table 2.

Comparison of serum IL-2, IL-4, IL-6, and Gas levels between the two groups before and after treatment
Prior to treatment, there was no significant difference in serum IL-2, IL-4, IL-6, and Gas levels between the two groups ($P>0.05$). After treatment, the levels of serum IL-2 in the two groups were significantly higher than those before treatment. The levels of IL-4, IL-6, and Gas were significantly lower and more obvious in the treatment group with a statistically significant difference ($P<0.05$). The results are presented in Table 3.

Comparison of skin lesion area scores between the two groups before and after treatment
Following treatment, the skin lesion area scores of the two groups were significantly lower than those before treatment. Moreover, the level of decrease in the treatment group was more significant and carried statistical significance ($P<0.05$). The results are provided in Table 5.

Table. 2: Comparison of clinical efficacy between two groups of patients; no. of cases (%).
Note: Total effective rate=$(cure+obvious effect+effective)/Total number of cases per group (n)×100%.

Table. 3: Comparison of serum IL-2, IL-4, IL-6, and Gas levels between the two groups (X±s).
Note: *represents comparisons with the indexes before treatment, $P<0.05$. # represents comparisons with the control group, $P<0.05$.

Table. 4: Comparison of clinical symptom scores between two groups before and after treatment (X±s).
Note: *represents comparisons with the indexes before treatment, $P<0.05$. # represents comparisons with the control group, $P<0.05$.

Table. 5: Comparison of skin lesion area scores between the two groups before and after treatment (X±s).
Comparison of adverse reactions between the two groups of patients

During treatment, the main adverse reactions occurring in the patients included menstrual disorder, dizziness, nausea, and dry mouth, among others. The incidence of such adverse reactions was 5.28% in the control group and 2.64% in the treatment group, and no significant differences were observed between the two groups (P>0.05). The results are provided in Table 6.

<table>
<thead>
<tr>
<th>Groups</th>
<th>n</th>
<th>Menstrual disorder</th>
<th>Dizziness</th>
<th>Dry mouth</th>
<th>Nausea</th>
<th>Total incidence rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>61</td>
<td>1 (1.33)</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>1 (1.31)</td>
<td>2 (2.64)</td>
</tr>
<tr>
<td>Control</td>
<td>61</td>
<td>2 (2.63)</td>
<td>0 (0.00)</td>
<td>1 (1.32)</td>
<td>1 (1.33)</td>
<td>5 (5.28)</td>
</tr>
</tbody>
</table>

\[ \chi^2 = 1.578 \]

\[ p = 0.209 \]

Table. 6: Comparison of adverse reactions between the two groups; no. of cases (%).

Discussion

Anal eczema is a cellular immune skin disease that occurs in and around the anus. It is also called “wet sores disease” and “general papular eczema” in TCM. At present, the pathogenesis of anal eczema remains unclear, and the disease may be caused by internal and external interactions\(^3\). TCM studies suggest that anal eczema is related to factors such as wind, dampness, and heat evil, among others. It is believed that defensive qi acts on the muscle surface and protects it from external wind, dampness, and heat evil qi. If there is insufficient defensive qi, it can make evil qi immerse and turn to sores. If internal heat evil steam dampness is about to emerge, external wind evil attacks the surface and attempts to enter. However, the internal evil spirit does not come out, and the exterior evil does not enter. Mental stress, work-related disorders, and poor mental state will cause anal eczema\(^4\). TCM treatment advocates the elimination of aetiology, such as maintaining a comfortable mood, eating less, or not eating raw, cold, greasy, spicy, or excitant food. Traditional Chinese medicine often uses clearing heat, dryness, and dampness, dispelling wind, and itching cessation as the treatment method\(^5\).

Triamcinolone acetonide acupoint injection combined with compound Kugan mixture for the treatment of anal eczema is based on the characteristics of patients with anal eczema. Referring to the pharmacological research results of modern Chinese medicine, the Chinese herbal medicine prescription with the effect of dispelling wind, clearing away heat, detoxifying, dryness, and dampness is selected to achieve the purpose of treating anal eczema. Moreover, the Quchi point is the silent acupoint of the Yangming large intestine meridian, which can disperse wind, clear heat, and activate blood\(^6\). Notably, compound triamcinolone acetonide acetate solution is a long-acting glucocorticoid that can reduce the permeability of capillary wall, inhibit inflammatory reaction, prevent the formation of oedema\(^7\). Fumigation wet compress involves performing fumigation on the affected area by using a decocted compound Kugan mixture and directly applying the mixture to the affected part after the liquid medicine is cooled. The Radix sophorae flavescentis in the compound Kugan mixture has the effect of clearing heat and dampness, antibacterial and anti-inflammatory properties and treating skin pruritus. Moreover, Glycyrrhiza uralensis can be used for carbuncle anthrax and ulcers and has the effect of clearing heat and detoxification but can also adjust the properties of various drugs\(^8\). Rhubarb can cool blood and detoxify, and can also treat damp-heat jaundice, carbuncle, and furuncle. Alum is cold-natured, and has an antibacterial effect that is convergent and haemostatic. Radix sapsoshnikoviae, also known as anise, is sweet in taste, tepid-natured, and can dispel wind to relieve the surface, remove dampness to relieve pain, and provide spasmylosis. Phellodendron can clear heat and detoxify, cure heat dysentery, improve microcirculation, and promote wound healing. Herba lycopi is warm-natured and has the function of activating blood circulation to remove blood stasis, reduce swelling. Poria cocos has an obvious enzyme-lowering effect, which can improve microcirculation and immunity\(^9\). Bighead Atractylodes rhizome is sweet in taste, warm-natured, and has the effect of strengthening the spleen and tonifying the stomach, clearing free radicals and anti-lipid peroxidation\(^10\). Tangerine peel has the function of a cholagogue, enhancing immunity and improving the function of many types of receptors and enzymes, thus promoting the metabolism of lipid. Rhizoma atracylodis is bitter in taste, warm-natured, and functions by dispelling wind and cold, drying damp, and strengthening the spleen.

The results of the present study have demon-
strated that the total effective rate of the treatment group was 95.08% following treatment, which was higher than that of the control group (8.61%, P<0.05). The scores of clinical symptoms and lesion area in the treatment group were significantly higher than those in the control group (P<0.05). It is suggested that the combination of various drugs can enhance the immunity of the human body, improve microcirculation, fundamentally strengthen the stimulation of drugs to affected areas, reduce the toxic effect of antihistamine drugs, and thus achieve a good therapeutic effect to successfully treat anal eczema.

It has previously been determined that immune regulation in the human body has a very close relationship with the levels of serum IL-2, IL-4, IL-6, and Gas\(^{11}\). Anal eczema, as a cellular immune allergic disease, is closely related to the levels of these factors. Notably, IL-2 is an immunomodulatory factor that has a very significant promotive effect on T-cell proliferation and the enhancement of natural killer cells (NK)\(^{12}\). IL-4, secreted by auxiliary T-lymphocyte 2 (Th 2), can induce immunoglobulin E (Ig E) and increase the level of Ig E\(^{13}\). IL-6 is produced by various cells, such as macrophages, T-lymphocytes, and B-lymphocytes, and can stimulate the proliferation of cells participating in the immune reaction. This is the main cytokine of the inflammatory reaction, and it can be used as an auxiliary index of some inflammatory diseases\(^{14}\). Gas is a factor that stimulates gastric acid secretion from the gastric antrum mucosa to blood. It is a powerful transmitter of the central and peripheral nerves\(^{15}\), and it is positively correlated with the degree of anal eczema. As such, when the condition of anal eczema patient becomes more serious, Gas level inside patient’s body increase.

The present study demonstrates that, following treatment, the levels of serum IL-2 were significantly higher than those before treatment, while levels of IL-4, IL-6 and Gas were significantly lower. Moreover, the total effective rate of the treatment group was higher than that of the control group. As such, the clinical effect of triamcinolone acetonide acupoint injection combined with compound Kugan mixture on anal eczema was confirmed.

In conclusion, through investigating changes in clinical curative effect, lesion area score, TCM clinical symptom score, and serum IL-2, IL-4, IL-6, and Gas levels in the two groups (treatment and control) before and after treatment, triamcinolone acetonide acupoint injection combined with compound Kugan mixture is proven to be effective for treating anal eczema with an improved curative effect, better clinical effect, and improved quality of life for patients. However, due to the small sample size and relatively short time scale, the long-term effects of the study must be further explored.

References


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