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Revolutionizing atopic dermatitis treatment: The efficacy of modified Qingxin decoction

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Abstract: We aimed to explore the Modified Qingxin Decoction for Invigorating the Spleen (MQDIS) in the treatment of atopic dermatitis (AD) the efficacy and safety. We selected AD192 patients treated from June 2018 to June 2023 as a retrospective case-control study, and divided the patients into the observation group and the comparison group with 96 cases. Patients in the control group received conventional treatment. Observation group was treated with MQDIS on the basis of comparison group. Symptoms and signs, Scoring Atopic Dermatitis Index (SCORAD) score, itch score, dryness score and quality of life index were analyzed in the two groups. The improvement of skin area, severity, pruritus and sleep in the comparison group was better than that in the observation group, especially in the severity and sleep, and the statistical difference was very significant.($P_{\text{-value}}$<0.05).SCORAD score and itch degree of both groups decreased, the difference was statistically significant.($P_{\text{-value}}$<0.05).MQDIS for treating AD had a good effect on improving various points of skin lesion, dry points and quality of life, and the recurrence rate was lower, it was safe and effective.

Keywords: Atopic dermatitis; modified qingxin decoction for invigorating the striking; itching degree; clinical effect; security

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INTRODUCTION

Atopic Dermatitis (AD) is a chronic, recurrent inflammatory skin disease characterized by intense pruritus, dry skin, and eczema-like lesions (Pan *et al.,* 2024). The global incidence of AD is increasing year by year, with an estimated prevalence ranging from 15% to 30% in children and 1% to 10% in adults (Silverberg *et al.*, 2022). This widespread condition seriously affects the quality of life of patients. At present, the treatment for moderate and severe AD mainly relies on drugs such as glucocorticoids and immunosuppressants, but long-term use of these drugs may lead to adverse reactions and complications (Silverberg *et al.,* 2022).

Currently, treatments for moderate to severe AD primarily involve medications like glucocorticoids and immunosuppressants. However, long-term use of these drugs can result in numerous adverse reactions and complications, such as skin thinning, steroid acne, hyperglycemia, decreased bone density and a range of symptoms due to high cortisol levels, including weight gain, muscle weakness, and hypertension. While immunosuppressants effectively reduce inflammation, they also increase susceptibility to infections, may cause kidney or liver damage, and could lead to reduced blood cell production, resulting in anemia, leukopenia, and thrombocytopenia.

In Traditional Chinese Medicine (TCM), the development of atopic dermatitis (AD) is linked to heart fire hyperactivity and dampness from spleen deficiency (Chen *et al.,* 2022; Wang *et al.,* 2023). The treatment approach involves clearing heart fire and bolstering the spleen to eliminate dampness (Li *et al.,* 2021; Zhang *et al.,* 2022; Chovatiya and Silverberg, 2022). Modified Qingxin Decoction for Invigorating the Spleen (MQDIS) is a TCM prescription designed to clear the heart, remove dampness, and strengthen the spleen, providing a solid theoretical foundation for AD treatment (Chen *et al.,* 2022; Wang *et al.,* 2023). Research has elucidated the pharmacological mechanisms of herbs in MQDIS, including the anti-inflammatory and immunomodulatory effects of *Radix Scutellariae* and the antiallergic properties of *Poria* (Li *et al.,* 2021; Zhang *et al.,* 2022). However, systematic clinical evaluations assessing the efficacy and safety of MQDIS for moderate to severe AD are still lacking (Zhang *et al.,* 2024).

This study aimed to assess the efficacy and safety of MQDIS in treating moderate and severe AD, aiming to offer an effective clinical treatment option. Our literature review revealed that MQDIS potentially regulates immunity, exhibits anti-inflammatory and anti-allergic properties, among others (Yuan *et al.,* 2024). Utilizing a retrospective case-control clinical trial design, this research seeks to further investigate the value of MQDIS in managing moderate to severe AD cases, providing a scientific basis for traditional Chinese medicine's role in AD treatment.

MATERIALS AND METHODS

Research Object

A retrospective case-control study was conducted on 192

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AD patients who fulfilled the 1994 British Williams diagnostic criteria between June 2018 and June 2023. Participants were randomly allocated in a 1:1 ratio to either the observation or control group, comprising 96 patients each. A computer-generated randomization sequence, stratified by age and disease severity, was employed for assignment. An independent statistician, uninvolved in patient recruitment or outcome assessment, managed the allocation list to maintain concealment. All patients' clinicopathological data and follow-up information were fully documented, and the patient inclusion screening process is illustrated in Fig. 1. All the included patients gave informed consent, and we obtained ethical approval from the Medical Ethics Committee, with the approval reference number: 20180121-AS.

Diagnostic Criteria

Based on Williams' diagnostic criteria (Williams *et al.,* 1994), a diagnosis was established if the patient reported itchy skin along with at least three of the following symptoms: primary occurrence of skin lesions in flexural areas like the inner elbows, ankles, or neck (including cheeks for children under 10); a history of asthma and/or allergic rhinitis, or a first-degree relative with allergies; extensive history of dry skin; dermatitis noted in flexural areas or, for children under 4, on the cheeks, forehead, and outer limbs; and symptom onset before age 2 (not applicable to children under 4).

Exclusion of inclusion criteria

Inclusion criteria for this study included participants aged 2-35 years with a disease duration exceeding 12 months and no prior systemic drug therapy. Voluntary participation was mandatory, with parental consent required for those under 18. Participants had to adhere to medical guidance and refrain from any treatments, including antihistamines, glucocorticoids, and immunosuppressants, in the two weeks preceding the study.

Exclusion criteria comprised individuals engaged in or having recently participated in alternative AD clinical trials within the last month, study staff directly involved in the research, and those unlikely to complete the study. Additionally, individuals unsuitable for the study regimen due to allergies, pregnancy, breastfeeding, or severe unstable primary diseases in vital organs, as well as those with concurrent skin conditions or infections, or involvement in other drug trials, were excluded.

Routine Treatment

Participants in the control group underwent standard treatment protocols. Adults and children over 12 years old were prescribed loratadine tablets (Keratan, produced by Schering-Plough Pharmaceutical Co., Ltd., Shanghai, China) at a dosage of 10 mg orally once nightly. For children under 12, loratadine syrup (also Keratan) was administered: those weighing over 30 kg received 10 mg daily, while those under 30 kg took 5 mg daily.For managing exudative and erosive skin conditions, a diluted solution of compound Huangbai liquid (Shandong Hanfang Pharmaceutical Co., Ltd., Sinopiate code Z10950097) was applied to the affected areas using six layers of gauze, soaked until saturation but not dripping, for durations of 10-15 minutes, one to two times daily. In cases of skin erythema, papules, dryness, and desquamation, snake yellow paste (a hospital preparation from Chengdu University of Traditional Chinese Medicine, Chengdu, China) was evenly applied to the affected skin as per the medication instructions.All patients attended clinic visits every two weeks and underwent a treatment course every four weeks, with a total of two treatment courses monitored throughout the study.

MQDIS Healing

The observation group received MQDIS treatment, which was compared to the control group (Li *et al.,* 2014). The modified Qingxin Decoction for Invigorating the Spleen consisted of the following herbs: *Herba Schizonepetae* (10 g), *Radix Saposhnikoviae* (10 g), *Rhizoma Dioscoreae* (10 g), *Processed Atractylodis Macrocephalae Rhizoma* (10 g), *Poria* (10 g), *Herba Junci* (10 g), *Plumula Nelumbinis* (10 g), *Radix Sophorae Flavescentis* (10 g), *Radix Scutellariae* (10 g), and *Radix Glycyrrhizae* (10 g) (see Fig. 2). Adjustments to this formula were made based on individual symptoms:Patients with bright red rash received additional *Buffalo Horn* (15 g), Rehmannia Glutinosa (8 g), and Tree Peony Bark (12 g).For severe itching, *Densefruit Pittany Root-bark* (12 g) and *Kochiae Fructus* (10 g) were included.Patients experiencing poor sleep and restlessness were prescribed *Gambir Plant* (15 g), Dragon's bones, Fossilizid (10 g), and *Suberect Spatholobus Stem* (6 g).

Dioscoreae Hypoglaucae Rhizoma (12 g) and *Rhizoma Atractylodis* (10 g) were added for excessive exudation.Dry skin conditions were addressed with *Chinese Angelica* (12 g) and *Suberect Spatholobus Stem* (14 g). Dosage adjustments were made according to age and weight. The decoction process involved soaking the herbs for 20-30 minutes, boiling with high heat, then simmering for 30 minutes. This process was repeated once, with the combined decoctions taken twice daily (approximately 200 ml each dose) 30 minutes after meals. Patients attended follow-up visits every 2 weeks, completing a 4-week treatment course. The study included a total of 2 treatment courses.

Observation Indicators

The SCORAD index, devised by the European AD Research Group (ETFAD) (Chopra *et al.,* 2017), evaluates atopic dermatitis through three primary dimensions: A, B, and C, encompassing the extent of skin lesions, their severity, and the subjective level of itchiness and sleep impact.Dimension A assesses the skin lesion area, assigning scores based on the proportion of affected body

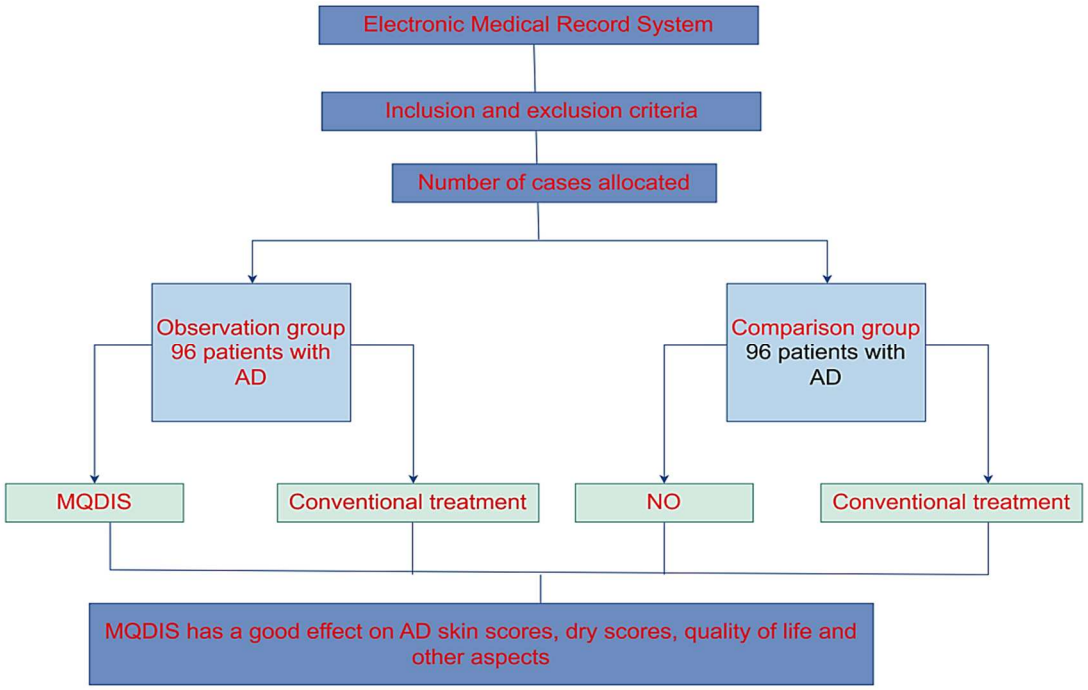

Fig. 1: Included patient screening process (This figure was drawn by Figdraw. ID: TTSTO86e88)

Fig. 2: Composition of MQDIS. (1. *Herba Schizonepetae*; 2. *Radix Saposhnikoviae*; 3. *Rhizoma Dioscoreae*; 4. *Processed Atractylodis Macrocephalae Rhizoma*; 5. *Poria*; 6. *Herba Junci*; 7. *Plumula Nelumbinis*; 8. *Radix Sophorae Flavescentis*; 9. *Radix Scutellariae*; 10. *Radix Glycyrrhizae*)

parts: head, face, and neck (3%), upper limbs (9%), trunk (18%), lower limbs (18%), and genitals (1%). Notably, the buttocks are considered part of the trunk, and dry skin without lesions is not scored. The maximum score for this dimension is 100 points.Dimension B examines the severity of skin lesions across six symptoms erythema, papules/edema, exudation/crusting, epidermal exfoliation/scratching, hypertrophy/lichenification, and dryness. Each symptom is rated on a 0-3 scale, totaling up to 18 points, where 0 signifies no rash, and 3 indicates a severe rash.Dimension C evaluates itchiness and sleep status on a 0-10 scale, summing up to 20 points. Here, 0 represents no itch or unaffected sleep, while a score of 10 reflects extreme itchiness or severely disturbed sleep.

Patients or their parents were requested to rate the average itchiness and sleep quality over the preceding three days. The dryness score was assessed across the patient's entire body using the following criteria (Dalvand *et al.,* 2014): A score of 0 indicated smooth skin with no signs of dryness; 1 point denoted slightly dry skin with occasional, non-uniform desquamation; 2 points reflected moderately dry skin with subtle, evenly spread desquamation that wasn't extensively covering the skin, with relatively fine scales; and a score of 3 signified severely dry skin, with widespread scaling, warped scale edges, a pale appearance of the skin surface, and possible cracking. Throughout the treatment period, the degree of dryness was comprehensively evaluated pre-treatment, and at the 4th and 8th weeks of treatment, with scores duly recorded. This evaluation facilitated the monitoring of treatment effects on dry skin conditions.

The Quality of Life Index (QoL) score, a widely utilized measure in dermatology for assessing quality of life (Hou *et al.,* 2017), was employed. For children and adolescents under 16, the Children's Dermatology Life Quality Index (CDLQI) questionnaire was used, involving questions for parents or guardians to evaluate the impact of skin conditions on the child's quality of life, typically completed

Fig. 3: Patients with bright red skin rash can add Chinese medicine. (1. *Buffalo Horn*; 2. *Rehmanniae Radix*; 3. *Moutan Cortex*)

Fig. 4: Chinese medicine that can be added to patients with severe itching. (1. *Densefruit Pittany Root-bark*; 2. *Kochiae Fructus*)

Fig. 5: Chinese medicine that can be added to patients with poor sleep and restlessness at night. (1. *Gambir Plant*; 2. *Dragon’s bones, Fossilizid*; 3. *Suberect Spatholobus Stem*)

by the caregiver based on the child's situation. For those aged 16 and above, the Dermatology Life Quality Index (DLQI) was applied. This index comprises 10 items spanning various life domains such as symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Each item is scored from 0 (no impact) to 3 (extreme impact), with total scores ranging from 0 to 30, where higher scores indicate diminished quality of life. The scoring interpretation is as follows: 0-1 indicates no impact; 2-6, slight impact; 7-12, moderate impact; 13-20, severe impact; and 21-30, very severe impact. Following 4 weeks of treatment, patients were re-evaluated and scores recorded to gauge treatment effects. A third assessment was conducted after 8 weeks of treatment to compare score changes pre- and post-treatment, thereby evaluating treatment outcomes.

STATISTICAL ANALYSIS

The data were imported into Statistic Package for Social Science (SPSS) 26.0 software (IBM, Armonk, NY, USA) for statistical analysis. Counting data were expressed as integers or percentages, chi-square tests (χ^2 tests) were used for comparison between groups, and rank-sum tests were used for ordered variables. Measurement data were expressed as mean ± standard deviation. For the data meeting the normal distribution, the two independent samples t-test is used to compare. If the data did not meet the normal distribution, the Mann-Whitney U rank sum test was used. P-value<0.05 was set as a statistically significant difference.

RESULTS

Comparison of clinical data of patients

The average ages of the Observation and Comparison groups were 12.47 and 12.45 years, respectively, with no statistically significant difference as indicated by a T-test P-value > 0.05. The gender distribution in both groups, with 51 males and 45 females in the Observation group, and 50 males and 46 females in the Comparison group, was similar, showing no statistical significance in a Chi-square test (P-value > 0.05). The mean disease duration was 7.55 years in the Observation group and 8.35 years in the Comparison group, with no significant difference between the two groups, as confirmed by a T-test P-value > 0.05. Regarding adverse reactions, 1.04% of the Observation group experienced abdominal pain and diarrhea compared to 3.12% in the Comparison group. No instances of drowsiness were reported in the Observation group, whereas 2.08% in the Comparison group exhibited this symptom. A Chi-square test revealed no statistically significant difference in adverse reaction rates between the groups (P-value > 0.05). Refer to Table 1.

Fig. 6: The patient has more exudates and can be added to the traditional Chinese medicine. (1. *Dioscoreae Hypoglaucae Rhizoma*; 2. *Rhizoma Atractylodis*)

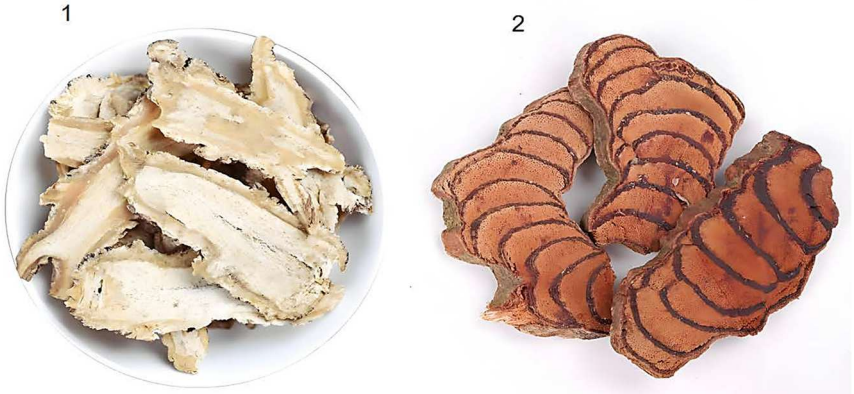

Fig. 7: Chinese medicine that can be added to patients with dry skin. (1.*Chinese Angelica*; 2. *Suberect Spatholobus Stem*)

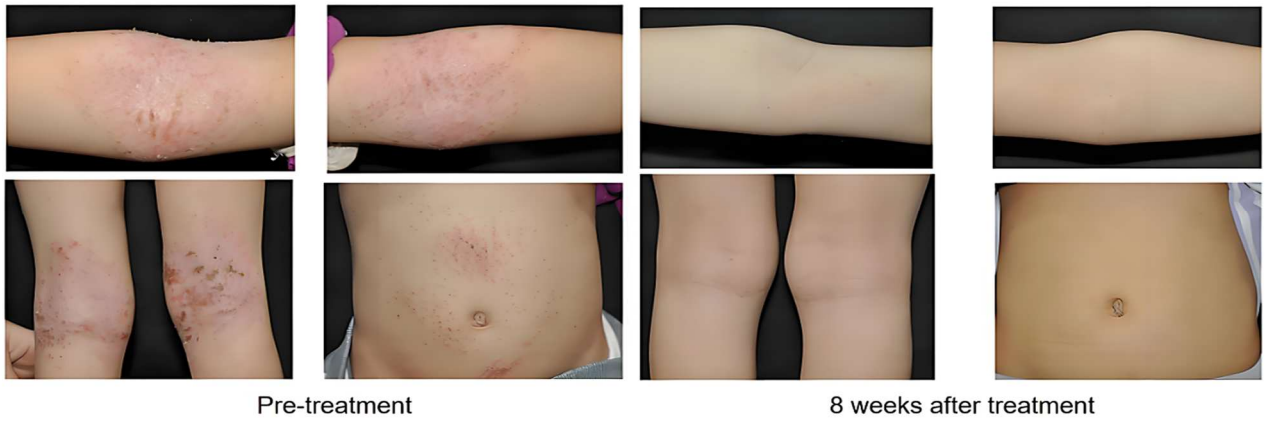

Fig. 8: Curative effect of typical cases before and after treatment

Comparison of symptoms and signs

Symptoms and signs were evaluated according to the SCORAD scoring system developed by the European AD Research Group (ETFAD). After Observation group pre-treatment, the lesion area was 26.80±7.38 and 26.33±5.27, respectively, which decreased slightly. Compared with group pre-treatment, the lesions were 27.00±6.51 and 24.53±6.36, which decreased significantly. There was no statistically significant difference in skin area between the two groups after pre-treatment ($P_{\text{-value}}$=0.842), but the difference between the two groups after post-treatment was close to significant ($P_{\text{-value}}$=0.033). It indicates that comparison group may be slightly better than Observation group in reducing the area of lesions. The severity scores of Observation group pre-treatment were 9.70±1.78 and 9.17±1.78, respectively, which decreased. The severity scores after comparison group pre-treatment were 9.80±1.86 and 7.90±1.79, with a large decrease.

The difference in severity between the two groups after pre-treatment became very significant in post-treatment ($P_{\text{-value}}$<0.0001), indicating that the comparison group was significantly better than the Observation group in improving severity. After Observation group pre-treatment, the itch scores were 5.53±0.97 and 5.00±1.17, which decreased. Compared with group pre-treatment, the itch scores were 5.86±1.17 and 4.33±0.80, with a greater decrease. The difference in itch scores between the two groups after pre-treatment was significant in post-treatment ($P_{\text{-value}}$=0.001), indicating that the comparison group was more effective in reducing itch. The sleep scores of the Observation group pre-treatment were 5.93±1.01 and 5.17±1.02, which showed improvement. The sleep scores after comparison group pre-treatment were 5.80±0.92 and 4.50±0.68, and the improvement was more obvious. The difference in sleep scores between the two groups after pre-treatment was very significant in post-treatment ($P_{\text{-value}}$<0.0001), indicating that the comparison group was better than the Observation group in improving sleep. See Table 2.

Comparison of itch degree scores

In the Observation group and comparison group, the scores of pruritus in pre-treatment were 7.10±0.97 and 7.25±0.91, respectively. The two groups had similar scores, indicating that both groups had similar levels of itching at the start of treatment. 2 weeks after treatment Observation group, the itch degree score decreased to 6.75±1.25, compared with 6.85±0.81 in the comparison group. The difference between the two groups was small and not statistically significant ($P_{\text{-value}}$=0.511). 4 weeks after treatment Observation group's rating dropped to 5.35±1.35, compared to 5.60±1.10 for the comparison group. The difference between the two groups remained insignificant ($P_{\text{-value}}$=0.161). Six weeks after treatment Observation group's rating dropped to 3.20±0.73, compared to 3.80±0.77 for the comparison group. The difference between the two groups began to be significant ($P_{\text{-value}}$<0.0001), indicating a more pronounced improvement in itching in the Observation group. Eight weeks after treatment Observation group's rating dropped to 1.75±0.64, compared to 3.35±0.67 for the comparison group. At this point in time, the difference between the two groups was very significant ($P_{\text{-value}}$<0.0001), and the Observation group was much better than the comparison group in reducing the degree of itching. See Table 3.

Comparison of SCORAD scores

The SCORAD scores of Observation group and comparison group before treatment were similar, 55.51±4.97 and 54.66±3.92, respectively. This suggests that the severity of the disease was similar in both groups at the start of the study. 2 weeks after treatment Observation group's SCORAD score decreased to 47.93±4.81, while comparison group's score was 50.09±3.80. At this point, differences between the two groups have begun to emerge, although they have not yet reached a very significant level (P-value=0.06). 4 weeks after treatment Observation group's score further decreased to 38.94±4.69, compared with 42.16±5.89 for the comparison group. At this point, the difference between the two groups becomes significant ($P_{\text{-value}}$<0.0001), indicating that the Observation group improved faster than the

comparison group. Six weeks after treatment Observation group's score dropped to 28.06±3.22, compared to 30.83±4.62 for comparison group. The difference remained significant ($P_{\text{-value}}$<0.0001), further confirming the treatment effect of the Observation group. Eight weeks after treatment Observation group's score dropped to 15.96±5.54, compared with 21.58±2.82. The difference at this point in time was the most significant ($P_{\text{-value}}$<0.0001), indicating that the Observation group has a more obvious advantage in long-term treatment. See Table 4.

Comparison of dry score and quality of life index between the two groups

Drying points after Observation group pre-treatment were 1.80±0.38 and 1.37±0.66, respectively, and drying points after post-treatment decreased. In comparison, drying scores after group pre-treatment were 1.73±0.10 and 1.60±0.48, respectively. Drying scores of post-treatment also decreased, but the decrease was smaller than that of Observation group. There was no statistically significant difference in drying scores between the two groups for pre-treatment ($P_{\text{-value}}$=0.082), while there was statistically significant difference in drying scores for post-treatment ($P_{\text{-value}}$=0.006). This indicates that the Observation group's improvement degree of post-treatment drying score is better than that of comparison group. The quality of life index after Observation group pre-treatment was 15.10±2.87 and 9.30±2.71, respectively, and the quality of life index after post-treatment was significantly improved. The life quality index after comparison group pre-treatment was 15.13±3.18 and 13.83±2.59, respectively. The life quality index of post-treatment was also improved, but the improvement was less than that of Observation group. There was no statistically significant difference in the quality of life index between the two groups for pre-treatment ($P_{\text{-value}}$=0.945), while there was statistically significant difference in the quality of life index for post-treatment $P_{\text{-value}}$<0.0001). These results indicated that the improvement degree of the Observation group in the post-treatment quality of life index was significantly better than that of the comparison group. See Table 5.

Typical case analysis

A 5-year-old Han Chinese girl was first seen on January 3, 2022. The patient's history shows frequent erythema and erosion of the head, neck, torso, and bent sides of the elbows and knees, accompanied by intense pruritus, over the past 5 years. According to her mother, the patient had facial erythema and pimples since birth, and had itching symptoms, which were relieved after the external washing treatment of traditional Chinese medicine in the local hospital, but it would recur every once in a while. A year ago, the patient experienced an increase in erythema, desquamation, and itching on the inside of the elbow, popliteal area, and buttocks, which oozed and crusted after scratching. The patient had sought medical treatment in many places, and had taken Cetirizine hydrochloride tablets, desloratadine tablets, dexamethasone ointment and desonide ointment, etc., although there was a brief effect, it was easy to relapse after withdrawal. He was diagnosed with AD and received MQDIS treatment. The patient was visited every two weeks, each course lasted for 4 weeks, and a total of two courses of treatment and observation were performed.

After 8 weeks of treatment, the patient's skin lesions improved significantly, with only a recent appearance of mild erythema and papules in the sockets of the legs, accompanied by mild itching and loss of appetite. The tongue image shows that the tip of the tongue is red, the tongue coating is thin and white, and the pulse is normal. According to the condition, adjust the treatment plan, strengthen clearing heat and dehumidification, and add digestive aid drugs. After treatment, most of the skin damage disappeared, the itch was greatly reduced, and only a few papules remained. Tongue image is still the tip of the tongue red, tongue coating thin white and greasy, pulse is stable. Continue to add or subtract drugs according to the original program, after more than a month of treatment, skin damage completely subsided, appetite increased. Follow-up for half a year showed no recurrence of the disease. The comparative pictures before and after treatment are shown in Fig. 8.

DISCUSSION

AD presents differently in patients of different ages, and the treatment principles should be adjusted accordingly (Li *et al.,* 2014). AD patients mostly present with symptoms in the acute phase, often seen in erythema and papules on the face and neck, sometimes accompanied by exudation, intense itching and continuous scratching, which makes children cry and feel uneasy and difficult to fall asleep at night (Napolitano *et al.,* 2022). These symptoms reflect the state of heart and liver fire and restlessness (Nakashima *et al.*, 2022). In contrast, adult AD patients have a longer course of disease, mainly in remission period, and long-term disease disturbance is easy to cause depression and anxiety, pruritus affects sleep, and also shows signs of heart and liver fire (Guttman-Yassky *et al.,* 2019). For the treatment of AD, both children and adults should pay attention to clearing heart fire and calming liver Yang (Ni *et al.,* 2023). Dry skin is a common symptom in AD patients in both acute and remission stages, especially in remission (Mandlik and Mandlik, 2021). At this time, the skin color becomes lighter, the skin becomes hypertrophic, and there may be moss-like changes, which are all manifestations of weakness of the spleen and stomach, insufficient qi and blood biochemistry, and skin dystrophy (Fang *et al.,* 2021). AD patients often inherit the physical characteristics of their parents, such as dampness and heat in the fetus, impaired spleen and stomach function, resulting in unfavorable transport and insufficient spleen soil, further affecting heart fire and forming a vicious cycle

of heart fire and spleen deficiency, which runs through the entire course of AD (Eichenfield *et al.,* 2022). In the treatment of AD, in addition to clearing heart fire and calming liver-yang, attention should also be paid to strengthening spleen and dampness, regulating spleen and stomach, so as to break the mutual causal chain between heart fire and spleen deficiency, so as to control the disease more effectively (Wang *et al*., 2022).

According to the theory of traditional Chinese medicine, the main etiology and pathogenesis of atopic dermatitis (AD) are hyperactivity of heart fire and dampness of spleen deficiency. Heart-fire extravagances lead to symptoms such as skin redness, swelling and itching, while spleen deficiency leads to endogenous moisture, further aggravating skin symptoms. Therefore, the key to the treatment of AD is to clear the heart fire and strengthen the spleen to dehumidify. The design of MQDIS is based on this theory. The prescription achieves the purpose of clearing heart fire, strengthening spleen and dehumidifying through the combination of various herbs. Specifically, each herb in Fang has its specific role, but their combination is able to create a synergistic effect that leads to a better treatment of AD. In the theory of traditional Chinese medicine, the compatibility of drugs is very important. Different combinations of herbs can enhance the efficacy and reduce side effects. The compatibility of herbs in MQDIS follows the following principles: the monarch medicine is the main medicine, the minister medicine assists the main medicine, and the supplementary medicine harmonizes the drugs, so that the medicine guides the drug to the lesion site. For example, *Radix Scutellariae*, as a royal medicine, has the effect of clearing heat and detoxifying. Tuckahoe (*Poria*) as a minister medicine, invigorating spleen and diuresis; *Radix Glycyrrhizae* (*Radix Glycyrrhizae*) is used as an enabling drug to harmonize other drugs. Certain herbs can be used in combination to enhance the effect. For example, *Radix Saposhnikoviae* (*Radix Saposhnikoviae*) and *Herba Schizonepetae* (*Herba Schizonepetae*) can be used together to enhance the effect of dispelling wind and dissolving surface. Certain herbs can be used in combination to reduce or eliminate toxicity. For example, licorice can alleviate the toxicity of other herbs. MQDIS has good efficacy and safety in the treatment of AD. For example, a retrospective case-control study showed that MQDIS significantly improved skin symptom scores, dryness symptom scores, and quality of life in patients with AD. In addition, the recurrence rate of this formula is low, showing a high safety and efficacy.

In the clinical trial of this study, we observed that by the 8th week of treatment, the Observation group was significantly better than the control group in improving symptoms and signs, SCORAD score, itch degree score, dry skin score, and quality of life. The analysis of the reasons for this result shows that the precise positioning of the treatment plan and the in-depth understanding of the etiological mechanism are key factors (Xiaoying *et al.,* 2023). From the perspective of modern medicine, MQDIS takes into account various pathological links in the treatment of AD pruritus (Ding *et al.,* 2023). Pharmacological studies reveal that the essential oil of *Herba Schizonepetae*, an effective component of traditional Chinese medicine *Herba Schizonepetae*, can reduce the content of prostaglandin E in inflammatory tissues by inhibiting the activity of cell membrane phospholipase A2, thus playing an anti-inflammatory role (Liu *et al.,* 2021). MQDIS plays a positive role in repairing the skin barrier function and increasing ceramide content in the stratum corneum. *Radix Sophorae Flavescentis* base can inhibit the expression of inflammation-related receptors, and *Radix Scutellariae* has pharmacological effect of inhibiting leukotriene synthesis (Ham and Kim, 2023). *Radix Glycyrrhizae* not only has anti-inflammatory and immune regulation effects, but also can increase the blood concentration of corticosteroids, thus further enhancing the improvement effect on pruritus symptoms (Liu *et al.,* 2021). MQDIS during the treatment of AD, effective control of the disease and significant improvement of symptoms were achieved through the multi-component and multi-pathway mechanism (Zhang *et al.,* 2024).

MQDIS therapeutic analysis was performed in this study. *Rhizoma Dioscoreae*, as a kind of food with the same origin as medicine and food, has a sweet taste, can tonify spleen and stomach, promote fluid and moisten lung, and has a good regulating effect on spleen and stomach weakness in AD patients (Zhang *et al.,* 2023). Largehead Atractylodes, sweet and warm in nature, is good at strengthening the spleen, invigorating qi and reducing water, while roasted Largehead Atractylodes has better effects in strengthening the spleen (An *et al*., 2020). *Poria*, sweet and calm, can not only strengthen the spleen, water and moisture, but also calm the heart and calm the mind. The combination of three drugs aims to strengthen the spleen and qi, while not causing diuresis and Yin injury, which is very suitable for the pathogenesis of AD patients (Haghnazar *et al.,* 2023). Typha latifolia, light in quality and mild in taste, can clear heart fire and relieve urination, and has a good effect on irritability and insomnia caused by hyperactivity of heart fire (Rolon-Cardenas *et al.,* 2022). *Plumula Nelumbinis*, a bitter and cold product, can not only clear the heart fire, but also calm the mind. When used with Typha latifolia, the effect of clearing the heart and eliminating irritability is mild (Stroppa *et al.,* 2020). *Plumula Nelumbinis* avoids the possible damage of the spleen and stomach caused by bitter cold drugs and helps to improve sleep and pruritus problems in AD patients (Chen *et al.,* 2021). *Radix Sophorae Flavescentis* and *Radix Scutellariae*, both bitter cold and dry dampness products, have the effect of clearing heat, detoxifying and relieving itching. When used together, the two drugs can not only clear the hot and toxic evil of relieving the heart meridian, but also balance the temperature of other drugs in the formula (Liu *et al.,* 2021).

Table 1: Comparison of clinical data between the two groups {$\bar{x}$±sd, [n(%)]}

Variables	Observation group (96)	comparison group(96)	t/x^2	P_{-value}
Age (years)	12.47±7.12	12.45±7.15	0.019	0.984
Gender (Male/female)	51/45	50/46	0.021	0.885
Duration of illness (years)	7.55±4.59	8.35±6.23	1.013	0.312
Adverse reaction			0.600	0.439
Abdominal pain and diarrhea	1(1.04)	3(3.12)		
drowsiness	0	2(2.08)		

Table 2: Comparison of symptoms and signs between the two groups

Groups	Skin lesion area		Degree of severity		Pruritus		Sleep	
	pre-treatment	post-treatment	pre-treatment	post-treatment	pre-treatment	post-treatment	pre-treatment	post-treatment
Observation group (96)	26.80±7.38	26.33±5.27	9.70±1.78	9.17±1.78	5.53±0.97	5.00±1.17	5.93±1.01	5.17±1.02
comparison group(96)	27.00±6.51	24.53±6.36	9.80±1.86	7.90±1.79	5.86±1.17	4.33±0.80	5.80±0.92	4.50±0.68
t	0.199	2.143	0.660	8.291	1.822	3.941	1.905	5.35
P_{-value}	0.842	0.033	0.132	<0.0001	0.070	0.001	0.058	<0.0001

Table 3: Comparison of itch degree scores between the two groups

Groups	Pre-Treatment	2 Weeks After Treatment	4 Weeks After Treatment	6 Weeks After Treatment	8 Weeks After Treatment
Observation group (96)	7.10±0.97	6.75±1.25	5.35±1.35	3.20±0.73	1.75±0.64
comparison group(96)	7.25±0.91	6.85±0.81	5.60±1.10	3.80±0.77	3.35±0.67
t	1.105	0.657	1.406	5.540	16.919
P_{-value}	0.270	0.511	0.161	<0.0001	<0.0001

Table 4: Comparison Of Scorad Scores Between The Two Groups

Groups	Pre-Treatment	2 Weeks After Treatment	4 Weeks After Treatment	6 Weeks After Treatment	8 Weeks After Treatment
Observation group (96)	55.51±4.97	47.93±4.81	38.94±4.69	28.06±3.22	15.96±5.54
comparison group(96)	54.66±3.92	50.09±3.80	42.16±5.89	30.83±4.62	21.58±2.82
t	1.315	3.452	4.190	4.819	8.857
P_{-value}	0.189	0.06	<0.0001	<0.0001	<0.0001

Table 5: Comparison of Dry score and quality of life index between the two groups

Groups	Drying Integral		Quality of Life	
	Pre-Treatment	Post-Treatment	Pre-treatment	Post-treatment
Observation group (96)	1.80±0.38	1.37±0.66	15.10+2.87	9.30+2.71
comparison group(96)	1.73±0.10	1.60±0.48	15.13+3.18	13.83±2.59
t	1.745	2.761	0.068	11.840
P_{-value}	0.082	0.006	0.945	<0.0001

Herba Schizonepetae, which tastes hard by temperature, can relieve surface and clear rash (Ding *et al.,* 2023). *Radix Saposhnikoviae*, *Radix Saposhnikoviae*, known as a moisturizing agent in wind medicine, is combined with *Herba Schizonepetae* to play the role of dispelling wind, clearing rash and relieving itching (Xiaoying *et al.,* 2023). *Radix Glycyrrhizae* plays a role in harmonizing the medicinal properties of various drugs in *Radix Glycyrrhizae*, enabling the whole prescription to work together to achieve the effects of clearing heat and relieving itching, purging fire and detoxifying, clearing the heart and strengthening the spleen, thus effectively improving the clinical symptoms of AD patients (Zhang *et al.,* 2024). The design of the entire MQDIS formula fully considers the physical characteristics and treatment needs of AD patients, reflecting the concept of TCM syndrome differentiation and overall conditioning.

This study has several limitations inherent to its retrospective case-control design. Selection bias may arise from the non-random allocation of patients into groups, as participants were divided based on historical treatment records. Additionally, recall bias could influence patient-reported outcomes, such as pruritus and sleep scores. To address these limitations, future prospective studies should incorporate randomization, blinding, and standardized data collection protocols. Randomization would minimize selection bias, while blinding of assessors and participants could reduce observer and reporting biases. Although this study observed significant efficacy of MQDIS in patients with AD over an 8-week treatment period, study period limitations prevented us from fully assessing its long-term effects and recurrence rates. Future studies should consider extending the treatment period to six months to one year, combined with long-term follow-up data, to further validate the sustainability and safety of MQDIS. In addition, long-term studies should focus on patient recurrence rates, the persistence of improvements in quality of life, and potential adverse effects to provide more comprehensive evidence support for clinical practice.

CONCLUSION

The Modified Qingxin Decoction for Invigorating the Spleen shows promise in treating Atopic Dermatitis, improving skin and dry symptom scores, as well as quality of life, with a low recurrence rate. This indicates its safety and effectiveness, warranting further exploration for clinical use.

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