

Combination of flying needle with Chinese Herbal Medicine in the treatment of Atopic dermatitis: A clinical trial

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Abstract: Atopic dermatitis (Atopic dermatitis, AD) is a kind of chronic recurrent dermatitis. So far, no curative treatment has been found yet. Acupuncture, as a kind of alternative medicine, Flying Needle is a kind of acupuncture, which has a unique curative effectiveness in improving the skin lesion and itch. A single-center, prospective, randomized clinical design was conducted. The curative effect of the combination of Chinese herbal medicine and acupuncture for the treatment of Atopic dermatitis was assessed. Thirty (30) patients were treated with Flying Needle and Chinese herbal medicine. Because of personal reasons, one (1) dropped out. The patients accepted Flying Needle treatment 3 times a week and the internal medicine 3 times daily for in all 12 weeks. Before treatment, and after treat 4,8 and 12 weeks, assessments were performed. After treat 12 weeks, all patients of SCORAD score were dropped, with the mean SCORAD score declining to 19.58±12.21. The recovery and removal rate comparison (* $\Delta x^2=5.28, P=0.03<0.05$). There are no side effects. The results hint that combine Flying Needle with Chinese herbal medicine are benefit on patients with atopic dermatitis and the effectiveness may better than oral medicine alone.

Keywords: Atopic dermatitis, Flying Needle, Chinese Herbal medicine

INTRODUCTION

Atopic dermatitis (Atopic dermatitis, AD), also known as the “ectopic dermatitis” (Yan 2012). The crucial symptom is itch, and it’s a kind of chronic recurrent dermatitis (Chen 2008). Researches have found that the incidences of Atopic dermatitis are gradually increased in recent 30 years (Robinson and Arno1d, 2010). As patients with long-term, repeated itching, rashes, drug side effects and discomfort, it seriously affect the patients’ physical and mental health (Chrostowska *et al.*, 2012). Even though, stubborn and chronic recurrent dermatitis had increased the patients and social economic burden (Carroll *et al.*, 2005).

So far have not yet fully cure and control the effective treatment of recurrence of Atopic dermatitis, antihistamines in the traditional western medicine treatment effect are not ideal, internal and topic of hormone or immune inhibitors side-effects, alternative medicine treatment have been widely concerned (Bielory *et al.*, 2002).

Both acupuncture and Chinese herbal medicine were viewed as classical Chinese medicine, which have been used for many years to treat diseases in China (Hanifin and Rajka, 1980). Acupuncture, as a kind of alternative medicine, it have unique curative effect in treatment itch of Atopic dermatitis (Pfab *et al.*, 2010) and had

accumulated a wealth of experience. In recent years, a large number of animal experiment have reported the effectiveness of acupuncture for Atopic dermatitis, but lack of large number of randomized controlled clinical trials (Park *et al.*, 2013). Therefore, it is necessary to verify the clinical studies on acupuncture for Atopic dermatitis.

MATERIAL AND METHODS

Inclusion criteria

In line with the western medicine diagnostic criteria and Traditional Chinese Medicine diagnosis standard; mild to severe degree of Atopic dermatitis; ages of 12 and 65; Signed informed consent, (<18) are signed by their families; Agree to the acupuncture treatment.

Exclusion criteria

Treatment with traditional topic therapy and/or oral Medicine or hormones in past 2 weeks before the recruitment; pregnancy; severe physical or mental illness; with other skin diseases or chronic inflammatory dermatoses.

Drop out of criteria

Adverse reactions or unknown reason to exit the participants; unable to judge the curative effectiveness and safety of rendering for the information is not complete;

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#Both Xiaohong Quan and Shenrong Cheng contributed equally to this study and are co-first authors

Fall off of criteria

Can't cooperate with treatment, quit the healer

Group and the sample size

This clinical study lasted for 12-week period of treatment. There will be 60 patients included, using a randomisation sequence to randomly divided the patients into treatment group (combination of Flying Needle with oral Medicine) and control group (oral Medicine group) according to the proportion of 1:1. Two groups' baseline characteristics are balanced.

Study design

The study was a single-center clinical trial, designed retrospective and randomized. It was aim to verify the clinical efficacy and safety of acupuncture for mild-to-severe Atopic dermatitis, and to observe its degree on the improvement of the itch and skin lesions. The control group: taking improvement of spleen to eliminating dampness herbal medicinal broth (herbal medicinal are poria, coicis semen, Atractylodis macrocephala glycyrrhizae), combined with regular skin-care. Each patient received 3 times-a-week treatment, 4 weeks for 1 course, this study continue for a 3-month cycle treatment, a total of 36 sessions

The treatment group: on the basis of control group with Flying Needle. Each patient accepted 3 times-a-week treatment with Flying Needle sessions (all of 36 times); When managed the acupuncture, use the wrist and finger swing inertia to enhance the penetration force. Place needle obliquely next to acupuncture points, When move the hand to the acupuncture points, rotate the needle to a high speed before touch the acupuncture points, With the hand moving inertia, insert the needle to the acupuncture points by finger and wrist. Do mild reinforcing-reducing method for the patients. After getting needle sense, thrust slowly and lift slowly, rotate needle at a moderate angle ($\leq 360^\circ$) to operate needle. The operation could not lead to marked needle sense or any comfortlessness. each therapy lasted 30 minutes. needle material are not limited. Points are LI11, ST36, SP9 and SP10. We changed the needling manipulation and points of acupuncture according to the patient's clinical status, based on the basic theory of Traditional Chinese Medicine.

Outcome measures

The primary outcomes to evaluate the lesion area were defined as the reduction in the SCORAD score. Which is developed by the European Task Force and as a clinical tool to assess the extent, severity, and subjective symptoms of Atopic Dermatitis?

The curative effect have four degree according to nim horizon, based on the curative effect index. 90%-100% was "recovery", 60%-90% was "removal", 20%-

60% was "effective", <20% was "ineffective".

Curative effect index% = (SCORAD score before the treat-SCORAD score after the treatment)/SCORAD score before the treat x 100%.

Total effective rate as the Secondary one outcomes.

Total effective rate =(basic recovery case + removal case + effective case)/total number of cases x 100%.

Side-effect

Any adverse events or discomfort symptoms were observed at each visit. Adverse reactions observed: nausea, dizziness, vomiting, fatigue, headaches and so on.

Observation point

We considering a clinic observation form before the treatment, the SCORAD score were observed by two researchers before the treatment and at months 1, 2 and 3 patient compliance also were recorded.

STATISTICAL METHODS

Using SPSS 18.0 statistical package database, carries on the statistical analysis. Compared to within and between group. Mean \pm standard deviation are used to express all data in this study. All distributions were made bidirectional, and p-values > 0.05 or p-values > 0.01 were considered that the result is non- significant.

RESULTS

Patient characteristics

Patients with Atopic dermatitis were recruited from March 2013 to January 2014 in Guangdong hospital dermatology outpatient clinic and traditional therapy clinic. Baseline characteristics of the two groups before treatment in patients such as gender, age, course and SCORAD score. Thirty (30) patients were recruited to the treatment group; twenty-nine (29) of them accepted the all the treatment. One (1) did not because of personal reasons, their average age were 24.3 years, there were 13 men and 16 women; Thirty (30) patients were recruited to the control group; all of them completed the study. The mean age was 23.45 years, there were 14 men and 16 women (P>0.05) (table1) showed that the difference between two groups were tiny enough, and it is comparable.

Comparison of SCORAD score

Compared with before treatment, all patients experienced a significant reduction in SCORAD score, changes were statistically significant (P<0.05). But treatment group compared with the control group after treatment of 4 weeks and 8 weeks, the SCORAD score change have no statistical significance, (P>0.05). After the end of therapy, all patients of SCORAD score were dropped, with the average SCORAD score declining to 19.58 \pm 12.21

($P < 0.05$) when compared with the control group ($P < 0.05$) (table 2).

acupuncture is the unique treatment of Atopic dermatitis. Flying Needle as one kind of the acupuncture therapy, it

Table 1: Subjects' baseline characteristics

Group	Cases	Sex		Age (year)	Course of disease (year)	SCORAD score
		Male	Female			
Treatment	29	13	16	24.30±9.18	12.65±8.01	54.21±14.88
Control	30	14	16	23.45±8.12	13.65±6.76	55.42±18.69

Table 2: SCORAD scores before and after treatment

Group	Case	Before treatment	After 4 weeks	After 8 weeks	After 12 weeks
Treatment	29	54.21±14.88	40.50±19.27	33.15±15.96	19.58±12.21
Control	30	55.42±18.69	45.56±18.37	34.85±15.82	28.07±14.15

Table 3: Two groups of effect rate and contrast

Group	Recovery	Conspicuous Effect	Effective	Ineffective	Recovery rate	Removal rate	Total effect rate
Treatment	6	16	3	4	20.7%	75.9%	86.2%
Control	3	11	8	8	9.10%	46.7%	73.3%

Total effective rate

Two-group total effective rate comparison ($*\Delta x^2=1.50$, $P=0.21 > 0.05$), showed that difference between two groups was non-significant. But the recovery and removal rate comparison ($*\Delta x^2=5.28$, $P=0.03 < 0.05$), suggest that the effectiveness of combine Flying Needle with oral medicine are better than oral medicine alone (table 3).

Side-effect

There were no any side-effect were seen in the study.

DISCUSSION

Oral Chinese Herbal Medicine and traditional therapy have been used in China since 100BC. They are frequently used in many areas, especially allergic diseases. Atopic dermatitis as a recurrent dermatitis, So far have not yet fully cure and control the effective treatment of recurrence of it.

Wetness aggregates and spleen deficient are one of the basic etiology and pathogeneses of Atopic dermatitis. it throughout the entire process of disease development, especially the middle to later periods of the disease (Fan 2003 and Zhou 2000). Due to the spleen deficient, it lost their basic function, then induce into the skin disease, characterized by repeated scratching, moss samples, rash with lighter color, erosion and so on. This is the advantage of acupuncture and moxibustion therapy, the so-called "for the micro needle to the outside, soup to the inside", by choice the tai-Yin and Yang-Ming meridian acupuncture points can stimulate main and collateral channels, viscera of the body conditioning, improve the function of the spleen and stomach. It is visible that

has unique advantages, such as painless, speediness, sterile and effectiveness. Lung connect to the fur, spread the cold origin of fur to the outside; Li 11 can keep the balance of Qi and Xue. SP9 and ST36 can improve the function of spleen. The pathogenesis of Atopic dermatitis is complex, there are often many and miscellaneous symptoms such as dry skin, so, take the acupuncture points to improve the function of the spleen, effectively improve atopic dermatitis patients, symptoms, promote disease rehabilitation.

This study generally deduced that combine Flying Needle with Chinese herbal medicine are benefit on patients with Atopic dermatitis and the effectiveness may better than oral medicine alone. To our research field, as a clinical test, this design is the first to observe the curative effect of combined Flying Needle therapy with Chinese Herbal Medicine in adult Atopic dermatitis patients. This study hint that for Chinese herbal therapy in patients with moderate to severe Atopic dermatitis, take effective acupuncture therapy can not only improve the removal and recovery rate, but also can effectively improve the lesion area in patients with Atopic Dermatitis.

CONCLUSION

In summary, the study suggests that acupuncture may be effective in the treatment of Atopic dermatitis and it has no adverse reaction. Due to the limited research time, this study did not forward curative effect observation and tracking. In Future clinical test, we need design larger-scale studies to observe the curative effect of acupuncture in Atopic dermatitis patients. More rigorous RCTs and research are needed for stronger evidence regarding the

efficacy and safety of acupuncture treatment for Atopic dermatitis of clinical trial settings. In future researches, a standardized point scheme will as a special selection of acupuncture points.

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