

A Comparative Clinical Trial on Leech Therapy and Unani Herbal Formulation on Atopic Eczema

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Abstract

Introduction: *Nare Farsi* (Atopic Eczema) is an inflammatory skin reaction characterized by itching, redness, scaling, cracking and oozing. constitutes a major proportion of all skin diseases and affects QoL. Regimental therapy plays an important role in skin diseases especially in Atopic Eczema.

Material and Methods: This trial was conducted to evaluate the effect of Leech therapy and Unani Herbal Formulation on Atopic Eczema in the Department of *Moalijat* (General Medicine), Govt. Nizamia Tibbi College, and Hyderabad during the year of 2005-2008. The study consisted of 4 years of age were included. were given Oral decoction of unani drug along with local application of leech in test group, whereas in comparative group oral and local unani herbal formulation were given for 4 weeks and followed up one month after trial.

Results: Results were assessed by using the Student's 't' test and the two groups were compared regarding relief of symptoms by X² test. The results showed a significant improvement in sign and symptoms both in the test group (p<0.01) and in the comparative group (p<0.05).

Conclusion: Local application of leech on *Nare farsi* was found better in comparison to local application of unani herbal medicine.

Keywords: *Nare Farsi*; Atopic eczema; Morbid humors; Leech therapy; *Irsle Alq*; Unani herbal formulation

Introduction

Eczema is a chronic inflammatory skin ailment characterized by Itching, burning sensation, erythema, scaling, cracking, crusting swelling, papules, weeping and oozing of the skin. It is mostly seen on folds of elbows or behind the knees. The lesions vary from vesicle to lichenification of skin on a background of poorly demarcated redness [1]. Atopic eczema may be associated with other atopic diseases such as hay fever and asthma. People with atopic eczema also have a dry skin tendency, which makes them vulnerable to the drying effects of soaps. It starts in early life; about 80% of cases had it before the age of 5 years [2-4]. Overall prevalence of 15-20% is reported in children aged between 7-18 years [5-7]. The prevalence of all form of eczema was 18 per 1000; seven of them had Atopic Dermatitis, Hand Eczema, Dyshydrotic Eczema and Nummular Eczema each accounted for about two per 1000 [8,9]. It is due to genetic predisposition, allergy and debility. Climate and psychological factors can play an important role in occurrence of eczema, there is usually a family history of allergic asthma, hay fever etc. [10-12]. Climatic extremes like heat, dampness, sever cold and psychological stress promotes the development of eczema. In dry winter of northern India cracking of the integument of exposed parts may result in eczema [11].

According to unani philosophy *Nare Farsi* results from admixing of *safra wa sauda Mohratiqua* (Abnormal yellow and black bile) with blood. These abnormal humors alter the *mizaj* of blood as well as the organs gets nourishment from it. Body's corrective force (*Tabiyat*) expels the abnormal humors towards skin, because expelled humors are highly irrigative and hot, hence they cause itching and burning sensation. The viscous part of these humors may conclude as scale or crusts and diluted hot part accumulated as vesicles [13-18].

Diagnosis of eczema is usually based on the sign and symptoms, family history, examination of skin and laboratory investigations like High serum IgE levels or high specific IgE levels [19-21]. It can be tested by radio-immuno absorbent assay [RAST test] of blood or indirectly by skin prick test. A peripheral blood eosinophilia may also be seen in eczema [22].

Various therapies have been used for this clinical condition but all are with poor response and limitations [19]. Treatment with Unani medicine is considered the best because of better acceptability, safety and efficacy, potency, low cost with least or no side effects. Many Unani herbal drugs like *Unnab*, *Shahatra*, *Mundi*, *Chariata* etc. are mentioned in the classical texts for skin diseases and they are in use and giving good results. Among them *Ushba Desi* for oral use was selected for the trial on the basis of its *Musaffi* (Blood Purifier), *Munziji wa Mushil* (Coctive and Purgative), *Mullyin* (Laxative), *Musakin Jild*, *Jali* (detergent), *Dafe Kharish* (Anti Itching), *Manaeth* and *Dafae Ufoonat* (Anti Septic) properties and on similar ground *Neem oil*

(*Azadirakta indica* Linn), Gandhak (Sulphur), *Kafoor* (Camphor) and *Ghekwar* (Aloe vera) were selected for local application [23,24].

According to the Unani system of medicine, leech therapy works on the principles of *Tanqiyae Mawad* (Evacuation of Morbid Humors) and *Imalae Mawad* (Diversion of humors) [25]. *Tanqiyae Mawad* means the resolution and excretion of morbid humors and excess fluids from the body, thereby maintaining the homeostasis in the quality and quantity of body humors, which are actually responsible for the maintenance of normal health. *Imalae Mawad* refers to the diversion of the morbid fluids from the site of affected organ to the site where from it is easily expelled from the body tissues [26]. Based on this holistic approach, leech therapy was selected for the management of *Nare farsi* (Atopic Eczema). The effectiveness of this therapy may also be attributed to the *Mokhaddir* (Sedative) and *Muhallil* (Anti-inflammatory) actions of saliva of leeches.

Objectives

1. To compare the efficacy and safety of Leech Therapy and local application of Unani Herbal Formulation in the management of *Nare farsi*.
2. To improve the Quality of Life (QoL) of the patients

Material and Methods

The clinical trial entitled “A Comparative Clinical Trial on Leech Therapy and Unani Herbal Formulation on Atopic Eczema” was carried out in Government Nizamia Tibbi College and Hospital during 2005-08. Total 40 patients of age group of 21-50 years with complaints of itching and burning sensation, erythema, scaling, cracking, crusting, swelling, papules, weeping and oozing of the skin were included in the study. They were randomly divided into test and comparative groups. A detailed history regarding age, socioeconomic status, occupation, presenting complaint with onset and duration was noted in Case Record Form [CRF]. Medical, Past and Family Histories were also recorded. Patients were thoroughly examined for assessment of their general health to rule out any other disease. Patients were investigated for ESR, Eosinophils and IgE before and after trial. After taking their informed consent they were included into the trial. At the time of their 1st visit the patients were provided a questioner and explained how to fill it. Before starting the trial Ethical Committee Approval was taken.

Study design: Randomized Comparative Clinical Study.

Duration of Study: One year

Sample size: 20 subjects in each group

Method of collection of data: (1) Sign and symptoms

(2) Laboratory investigations

Selection criteria:

Inclusion criteria: Both genders between the ages of 21-50 years. Complaint of Itching, burning sensation, redness, scaling, cracking, crusting, swelling, weeping and oozing of the skin

Exclusion criteria: Patient with systemic illness like HTN, DM, Impaired Renal or Hepatic functions. Patients with other skin diseases like Psoriasis, Ictheosis etc. Allergic Dermatitis.

Criteria for selection of the leech: Leech with small head and of small size like rat tail, having two golden lines on its back and of red colour were taken from clean water in which small frogs were present.

Intervention: In both groups decoction of 6 gram Ushba desi, was given per oral daily once in the morning. In the test group 4-6 leeches were applied on affected part once in a week. Leeches were allowed to suck the blood till they fall themselves wounds caused by leeches were washed and dressing was done with antiseptic lotion.

In comparative group paste of Gandhak, Gheekwar and Kafoor mixed in Neem oil and applied on affected part once daily after washing the affected part with distilled water in the morning.

Duration of treatment: Four Weeks

Follow-up: Once in a week for 4 weeks after the completion of trial

Criteria for efficacy

Relieved: 50% relief in sign and symptoms

Partially relieved: 25% relief in sign and symptoms

No response: any relief in sign and symptoms

Results and Discussion

In this study out of 40 patients 25 (62%) patients were female and 15 (38%) were males. Females are affected more than males. This finding was in accordance with the survey of Centers for Disease Control and Prevention (CDC).

Its prevalence was slightly higher in the age group of 31-40 years i.e 16 cases (40%) and least in the age group of 41-50 years i.e 10 cases (25%). Out of 40 patients 14 (35%) were in the age group of 21-30 years, 16 (40%) were between the age of 31-40 and 10 cases (25%) were in the age group of 41-50 years (Figure 1).

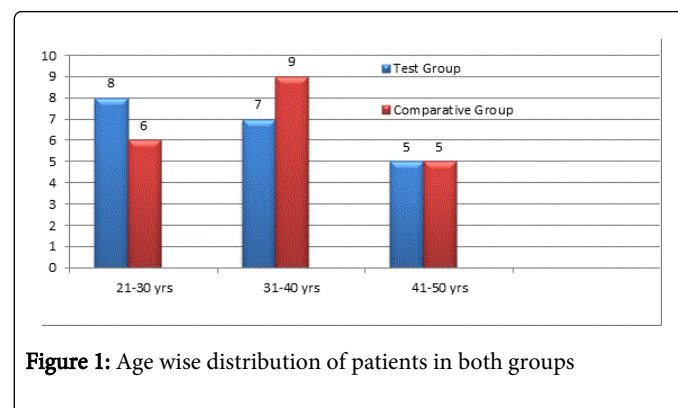


Figure 1: Age wise distribution of patients in both groups

Most cases of childhood eczema in any given community are of mild category. One recent study by Emerson and colleagues found that 84% of 1760 children aged 1-5 years from four urban and semi-urban general practices in Nottingham were mild, as defined globally by the examining physician, with 14% of cases in the moderate and 2% in the severe categories [27].

According to the Mizaj (Temperament) out of 40 patients 5 (12%) patients were of Damvi, 8 (20%) patients were of Balgami, 10 (25%) patients were of Safravi and 17 (43%) patients were of Saudavi mizaj. It means Atopic Eczema is more common in the patients with Saudavi mizaj and least in Damavi mizaj (Figure 2).

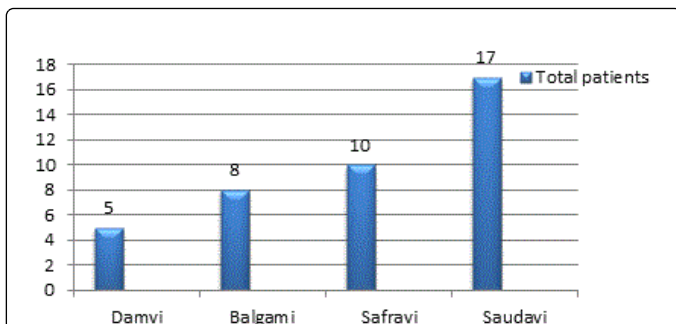


Figure 2: Mizaj (Temperament) of the patients

Therapeutic response of test group showed that out of 20 cases, 15(75%) cases were relieved from their symptoms, 3(15%) were partially relieved and 2 (10%) patient had no response. In comparative group 11(55%) patients relieved of the symptoms, 5 (25%) patients got partial relief and 4 (20%) patients didn't response. Results were assessed by using the Student't' test and the two groups were compared regarding relief of symptoms by X2 test. The result of the study showed a significant improvement in sign and symptoms in the test group ($p < 0.01$) as compared to comparative group ($p < 0.05$) (Figure 3).

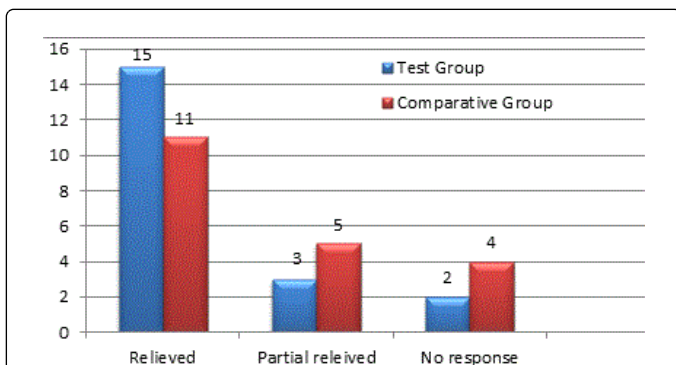


Figure 3: Response of the treatment

At one week follow-up, patients who received leech therapy along with unani drug reported significantly improvement in their sign and symptoms than those who were on only unani herbal medication. The leech group continued to report better function, better overall symptom relief and improved quality of life throughout the one month follow up period after the trial.

Summary and Conclusion

The present study revealed that Leech Therapy along with Unani Oral drug is safe, effective and of short duration therapy ($P < 0.01$) as compared to local application and oral administration of Unani Formulation ($P < 0.05$). No recurrence or exacerbation was reported by any patients after completion of trial up to one month of follow up. No

patients reported any adverse event throughout the trial and follow up duration. Eczematous signs and symptoms were improved in both groups, but rate of improvement was faster in test group. By this therapy eczema patients can be saved from exposure and from adverse effects of cytotoxic and steroid drug used in conventional system of medicine.

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