

## CLINICAL EFFICACY OF POLYHERBAL FORMULATION DERMIDOC CREAM FOR DERMATITIS

ALLAH NAWAZ, ZEESHAN AHMED SHEIKH, KAMRAN ALAM,  
RABIA BASHIR & KHAN USMANGHANI

Department of Research and Development, Faculty of Medicine, University of Toyama, Sugitani, Toyama, Japan

### ABSTRACT

The topical polyherbal formulation Dermidoc cream consisting of natural ingredients that have been clinically proved for its anti-itching and anti-inflammatory activity, has been advocated to treat skin ailments especially dermatitis. Dermidoc therapy was effective in treating dermatitis in this open clinical trial. The designed formulation application on affected part in dermatitis patients exhibited significant efficacy. Dermidoc cream consisting of *Cleome brachycarpa*, *Calendula officinalis*, *Psoralea corylifolia* and *Rheum emodi* wall. All the active material are cited that these have anti-inflammatory and counter irritant, wound healing, astringent, eczema, tissue repair, topical application of Calendula has been shown to enhance the granulation and epithelialization of damaged skin. Thirty two patients were treated with Dermidoc cream for three weeks, out of which 28 patients completed the study. It was observed that symptoms score reduced at end of 2 weeks onwards. The study design was prospective and opens as pilot study followed the inclusion and exclusion criteria. All the sign and symptoms were noted at baseline and at the end of 20 days treatment performance was evaluated. The statistical analysis was done by using Microsoft Excel2007 and SPSS version 18.0. It is concluded that Dermidoc cream has shown efficacy in mild to moderate cases on applying locally to the affected parts.

**KEYWORDS:** Astringent, Polyherbal, Anti-Inflammatory, Eczema, Dermatitis

### INTRODUCTION

Dermatitis means inflammation of the skin. It is sometimes called eczema. The main symptoms can include itching, cracking, blistering and ulceration. If someone has dermatitis the skin often looks red, sore and scaly. There are many different types of dermatitis but one of the main causes of the illness developing is contact with substances used at work. Every year 80,000 people suffer from skin problems caused, or made worse by work. These can be avoided. This booklet will help tell you how. There are two main types of dermatitis that can be caused by work. The first is called irritant contact dermatitis. This condition arises from working with substances that physically damage the skin when they came into contact with it. Among the chemicals that can cause this type of damage are many in common use such as acids and alkalis (e. g caustic soda, or cement) and organic solvents (like white spirit and alcohol). The second main type of dermatitis is called allergic contact dermatitis. This accounts for about 20 per cent of all forms of work-related dermatitis and is caused by certain chemicals called 'sensitizers'. This is where the body's immune system reacts to one of these substances. In many cases someone can work with a substance for years without any reaction and then suddenly develop dermatitis. Once a person becomes sensitized, even minute exposure may cause a severe reaction. It is quite common to find that once someone develops allergic contact dermatitis in reaction to one substance they also become 'cross-sensitized' to a range of substances. Contact with stainless steel, particularly when wet, is a very potent cause of sensitization. This is because of the nickel and chromium contained in the steel. Rubber (latex) in gloves and facemasks is also a big problem.

According to WHO reports, more than 80% people in Asia rely on traditional medicines for treatment of diseases. Such medicines are used for treating various chronic diseases including skin disorders and different infections [1].

The term 'traditional medicine' is a sum total of knowledge, skills and practices based on the theories, beliefs, and personal experiences indigenous to different cultures, that are used to maintain health, prevent disease spread, minimize disease or treat it completely both physical and mental wellness. Not only in underdeveloped countries but also in developed countries a large proportion of population relies on the herbal remedies.

Herbal medicine is the most popular form of traditional medicine with a long history. The information is transmitted from one generation to another. Different herbs show variable therapeutic response. For example jujube extract is used orally by common people for treatment of eczema. In 90% cases, it was effective while in 10% it showed no effect. Same treatment showed very good efficacy in some individuals and had no effect in some other individuals [2, 3]. At present the only line of treatment for all this is steroids and anti-histamines. Therefore, a clinical trial on the herbal preparation Dermidoc cream was conducted to find safe and alternative remedies to control the symptoms of different types of dermatitis. Dermidoc cream, an herbal preparation, has been promoted in to treat skin disorders especially dermatitis. It contains different herbs which have anti-itching, anti-inflammatory and wound healing properties. Dermidoc cream was proven that it has soothing effect as well as curing the symptoms of dermatitis.

### **Epidemiology**

Properly designed and conducted studies to determine the prevalence of dermatitis in the general community are few but the point prevalence of dermatitis in the U.K. is estimated at about 20%, with atopic eczema forming the majority [4]. The best studies show a point prevalence of hand dermatitis in South Sweden of 2% [5] and the lifetime risk of developing hand eczema to be 20% in women [6]. Irritant contact dermatitis is more common than allergic dermatitis; allergic dermatitis usually carries a worse prognosis than irritant dermatitis unless the allergen is identified and avoided. Contact dermatitis accounts for 4–7% of dermatological consultations. Chronicity is commonest in those allergic to nickel and chromate. Occupational dermatitis remains a burden for those affected. The most recent THOR /EPIDERM figures indicate that skin disease follows mental illness and musculoskeletal problems as a cause of occupational disease and accounts for approximately one in seven reported work related cases in the U.K [7]. Occupational dermatitis makes up the bulk of occupational skin disease (approximately 70%) with a rate of 68 per million of the population presenting to dermatologists annually and 260 per million to occupational physicians who tend to see earlier and less severe skin disease. The number of reports of allergic contact dermatitis in children is increasing [8]. The principle allergens which have been identified include nickel, topical antibiotics, preservative chemicals, fragrances and rubber accelerators. Children with eczematous eruptions should be patch tested, particularly those with hand and eyelid eczema [9].

### **Aim of Study**

This study was aimed to evaluate the clinical efficacy and safety of Dermidoc cream for the treatment of dermatitis.

## **METHODOLOGY**

### **Study Design**

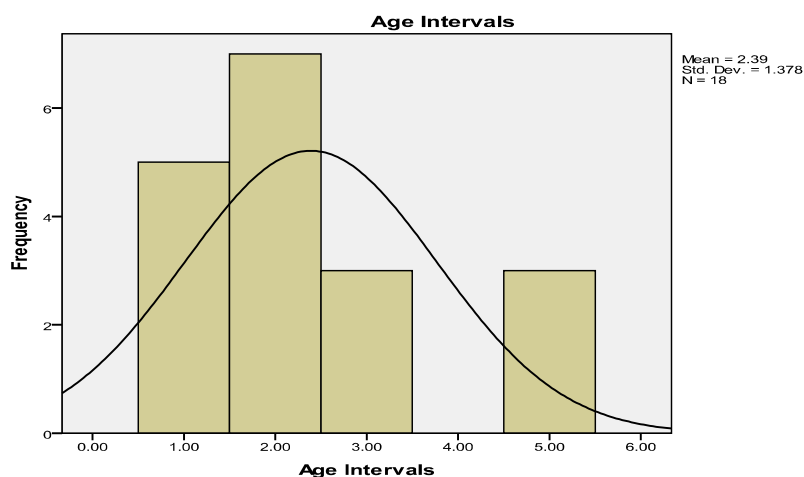
This study was prospective, open, non-comparative clinical trial. Clinical trial proforma, study protocol and product related information and informed consent forms were submitted to the Research and Development Department of Herbion Pakistan (Pvt) Limited.

## Work Plan

At first the patients suffering from complaints of dermatitis were screened out and initial history was taken on prescribed history sheet. Fifty two patients, presenting with dermatitis who attended the outpatient department at Sohail Memorial Hospital, Karachi, were included in the trial. The selected subjects were enrolled for clinical trial after taking informed consent from the patients. Thoroughly examined the patient at every follow up visit and compare the level of improvement from baseline symptoms. There were 16 males and 12 females aged between 18-62 years who were dispensed Dermidoc cream provided by Department of Research & Development, Herbion Pakistan Pvt Ltd. The patients were advised to externally apply Dermidoc cream polyherbal formulation gently on affected part 2-3 times daily for 10 – 20 days. They were advised to attend the OPD for follow up every week. They were evaluated at the end of 3 weeks for symptomatic relief of dermatological conditions. The lesions were assessed by different signs such as dermal oedema, pruritus, papules, vesicles, urticaria, tenderness, redness, epidermal thickening and pigmentation. The scaling of the lesions were assessed according to size area, excoriation, exudation, pinpoint haemorrhage and weeping exudation. The patients were advised to apply Dermidoc cream over the lesions. Patients who had infective dermatitis were prescribed antibiotics. The efficacy of Dermidoc cream was assessed by using scale *i. e* excellent (upto 70%), satisfactory (50%) and no effect. At the end of 20 days, the overall performance were evaluated and compared with baseline. Statistical evaluation of the collected data was done by using SPSS version 18.0 and Microsoft excels 2007.

## RESULTS

The clinical efficacy of polyherbal formulation Dermidoc cream in the management of dermatitis indicates that it has shown statistically significant results in reducing the symptoms and ailments. Out of the 32 patients, 28 patients completed the trial out of which 16 were males and 12 females. Results showed that there was a gradual decrease in the signs and symptoms of dermatitis from the 2<sup>nd</sup> week onwards. At the end of the trial patients showed significant decrease in the lesions ( $P < 0.05$ ). It was a pilot study conducted on 18 patients. The age limit was 18-62 years and duration was 10 day to 20 days. Age distribution of patients is given in figure 1.



**Figure 1: Age Distribution of Enrolled Patient**

None of the patients complained or exhibited any adverse effects. The Dermidoc cream has shown 26.6 % excellent, 53.3 % satisfactory result for treatment of dermatitis. Only 20 % of the patients had shown no effects.

## DISCUSSIONS

Different types of skin lesions characterize the various stages of dermatitis viz., acute, subacute and chronic dermatitis. The skin distribution pattern changes with age. During infancy and early childhood, dermatitis is usually more acute and mostly involves the face, scalp and extensor surface of the extremities. In adolescents and adults, the skin becomes lichenified and lesions occur mainly in the flexural folds of the extremities. The symptoms of dermatitis vary from person to person in various diseases. The most common symptoms are dry itchy skin, with rashes and cracks present over the skin. People with dermatitis seem to be sensitive to itching and feel the need to scratch. Skin in dermatitis can be changed by the pattern of scratching which results in skin infection. Improvements were attained in most of the symptoms such as pruritus, inflammation, oozing and scaling. The overall symptom score started reducing from the 2nd week onwards, and at the end of 2 weeks, it reduced by 52.08%. At the end of 3rd weeks, it reduced by 73.23%. There was complete absence of symptoms at the end of the study, which was 83.46% while the remaining symptoms were only marginal. The patients also reported that due to the alleviation of the symptoms, the patients attained improvement in mood symptoms, such as anxiety, depression and stress. This formulation could have benefit to act as smoothening and soothing effect thereby bringing down the symptoms of dermatitis.

In this clinical trial, skin irritation presented itself in a number of ways. The most common symptoms were itching, scales, blisters, thickened skin, flakes and colour changes. No predominant age or age group was more affected by dermatitis, different forms of dermatitis affect different ages, but we enrolled the patients with age range between 18-62 years. Both sexes are equally afflicted with dermatitis and variations are seen based on the individual differences in exposure to the allergen or due to the skin variations between men and women.

## CONCLUSIONS

It is concluded that Dermidoc cream has shown efficacy in mild to moderate cases on applying on affected parts. There were no adverse effects seen in any of the patients.

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