

# Clinical efficacy and safety of herbal medicine Dermidoc in the management of atopic dermatitis versus allopathic medicine PolymixinB-bacitrin ointment

Muhammad Osama Alam<sup>1</sup>, EjazMohiuddin<sup>1</sup>, Shahab-ud- Din<sup>1</sup>,  
Muhammad Daniyal<sup>2</sup> and Khan Usmanghani<sup>2</sup>

<sup>1</sup>Hamdard Al Majeed College of Eastern Medicine, Faculty of Eastern Medicine, Karachi, Pakistan

<sup>2</sup>Department of Medical Affairs and Training, Department of Research and Development, Herbion Pharmaceutical (Pvt.) Limited, Karachi, Pakistan

**Abstract:** Atopic dermatitis (AD) commonly identified as eczema. AD is an inflammatory, long-lasting, highly pruritic reverting disease of the skin. AD is classified by disease of outer skin layer barrier function. AD is progress with Immunoglobulin E facilitated sensitization to food and environmental allergens. One study stated that more than 59.6% of teen-agers with AD are at high risk of develop asthma or rhinitis. Interaction between genes and environment increase the prevalence of AD. AD have three standard stages: infantile, childhood, and adulthood. AD sign and symptoms diverge extensively. AD can be present that simply affect the hand to where a patient presents with erythroderma. AD present with erythematous papules, extremely pruritic with serous exudate. Lichenified plaques and papules are symptoms of long lasting AD. Due to outer skin layer barrier dysfunction bacterial and viral infection risk is increased in AD patients. This study was directed on 100 patients in which 50 are PolymixinB-bacitrin group and 50 are Dermidoc group. Patients were selected after seeing inclusion and exclusion criteria and taking written informed consent. Dermidoc group expressively amended skin symptoms associated with AD comparing to the PolymixinB-bacitrin group. The Dermidoc cream is effective and well tolerated. The results were analysis using paired sample t-test. The p value is <0.05. Test group (Dermidoc) were significantly more effective than PolymixinB-bacitrin group.

**Keywords:** Atopic dermatitis, Dermidoc, herbal drug, PolymixinB-bacitrin, tropical creams, clinical trial.

## INTRODUCTION

Atopic dermatitis (AD) commonly identified as eczema. AD is an inflammatory, long-lasting, highly pruritic reverting disease of the skin. AD is classified by disease of outer skin layer barrier function. AD is progress with Immunoglobulin E facilitated sensitization to food and environmental allergens. One study stated that more than 59.6% of teen-agers with AD are at high risk of develop asthma or rhinitis. Interaction between genes and environment increase the prevalence of AD. AD have three standard stages: infantile, childhood, and adulthood. AD sign and symptoms diverge extensively. AD can be present that simply affect the hand to where a patient presents with erythroderma. AD present with erythematous papules, extremely pruritic with serous exudate. Lichenified plaques and papules are symptoms of long lasting AD. Due to outer skin layer barrier dysfunction bacterial and viral infection risk is increased in AD patients (Andrew *et al.*, 2011). AD is one of the most common skin disorder, affecting about 10-20% of youngsters worldwide, with an increasing prevalence rate in industrialized countries (Leung 2000). Although its pathogenesis has not been clearly defined, one possibility is an impairment of the adaptive and innate immune response by environmental and genetic factors (Grewe *et*

*al.*, 1998; B Homey *et al.*, 2006). The AD is the disease of young age and its intensity decrease with the age but it may be persistent in 10% of cases for the decades (Mcgregor *et al.*, 1995). The AD is preventable if patient avoid the environmental causes and use topical corticosteroids with emollients (Ring *et al.*, 1996; Przybilla *et al.*, 1994). Management about skin maintenance is also noteworthy. In acute phase of AD the efficacy and tolerability of corticosteroids is well documented (Niedner *et al.*, 1993), But on long term use their efficacy is unwell acknowledged (Degreef *et al.*, 1993). Significant features in the diagnosis of AD are a pruritic/lichenified eruption and a personal or family history of allergic expressions (e.g., asthma, allergic rhinitis, and AD). This fact should be consider that it has tendency to recur. AD appearances diverse in people at different ages and of different races. Because most patients have scaly dry skin at some point. Conversely, patients with acute flare-ups comes with erythroderma that are lachrymose, lustrous, or condense and with more protruding patterns and with inflamed swelling of the skin (Tierney *et al.*, 2006). In the past decade no positive laboratory or histological conclusions stated, that's why the diagnosis of AD is totally depends on sign and symptoms. Numerous collections of investigative standards have recognized (Brenninkmeijer *et al.*, 2008) e.g., the Hanifin and Rajka standards and a factual

\*Corresponding author: e-mail: m.osama.alam@hotmail.com

**Table 1:** Design of the study

Number of Drugs	1. Test drug 2. Control drug	1. Dermidoc cream 2. PolymixinB-bacitrin ointment
Total Patients	50+50	50 Dermidoc+ 50 PolymixinB-bacitrin
Number of Tests	History, Physical Examination Serum IgE	Follow up 1 week after treatment
Duration of Treatment	1 month	Post treatment follow up

**Table 2:** Test and Control drug ingredients

Disease	Test drug	Ingredients of Test drug	Control Drug
Atopic Dermatitis (Eczema)	Dermidoc	<ul style="list-style-type: none"> <li>o <i>Cassia tora</i> 2.5gm</li> <li>o <i>Calendula officinalis</i> 1.25gm</li> <li>o <i>Psoralea corylifolia</i> 2.5gm</li> <li>o <i>Rheum emodi</i> wall 1.25gm</li> </ul>	PolymixinB-bacitrin

resultant, simplified variety characteristic important and concomitant features, that are convenient in the clinical context. Important features are itching and serous discharge that can be acute, sub-acute, or chronic. The AD lesion can be present in any part of the body, infrequently they can be generalized to subordinate red rashes. AD features include generalized dry skin (ichthyosis), Lichenification (leathery), Excoriation (Scratched), Oozing/Crusting, Oedema (Swelling), Erythema (Redness). Occurrence of AD has shown a global upsurge in the past 29.8 years. In established states, it appears to upland now at 9.6-21.4%, while it is subordinate but endures to upsurge in numerous emergent countries (Deckers *et al.*, 2012; Williams *et al.*, 2008). In unevenly 59.8% of cases, the illness demonstrates throughout the first year of life (i.e., early onset), but it can start at any age (Illi S *et al.*, 2004; Garmhausen *et al.*, 2013). The initial findings of AD are dry skin and irregularity, but eczematous scratches characteristically do not transpire earlier to the second month of life. The progression can be incessant for extended phases or of a reverting–forwarding nature with frequent flare-ups (Illi S *et al.*, 2004; Garmhausen *et al.*, 2013). The AD is insignificant in about 81.2% of affected children (Ballardini *et al.*, 2013). This study conducted to evaluate the efficacy and safety of herbal coded Dermidoc cream in AD patients.

## METERIAL AND METHODS

This study was carried out on patients of age group 2 year to above 40 years. The patients are categorized into two different groups i.e. test group (Dermidoc) and control group (PolymixinB-bacitrin) on whom Dermidoc formulation and PolymixinB-bacitrin formulation are applied respectively.

### Selection criteria

Patients were selected for this study who were eligible for inclusion criteria. A patient questionnaire is use to record the response of the patients. The determination of the present study was to compare the Dermidoc cream with

PolymixinB-bacitrin cream so as to measure its ultimate effects for its therapeutic meaning. This study in controlled study, including two groups one receive the Dermidoc cream and other receive the PolymixinB-bacitrin cream to establish efficacy and safety by standard parameters. The patients suffering from any other skin disease, diabetes, hypertension, renal diseases, severe psychiatric disorders, hepatitis and any type of immuno compromised patients *i.e.* HIV were excluded from the study and pregnant women excluded. The clinical trial proforma was filled with detailed history, signs, symptoms and prognosis on each follow up visit under the supervision of monitor physician and supervisor. The parameters that were taken in signs and symptoms for AD were dryness (ichthyosis), Lichenification (leathery), Excoriation (Scratched), Oozing/Crusting, Oedema (Swelling), Erythema (Redness) etc.

### Sample size

The study was directed on 100 patients in which 50 are Dermidoc group and 50 are PolymixinB-bacitrin group. These including all socioeconomic status patients at different health care centers i.e., at Sharafi Goth Naik Muhammad dispensary. In this study the patients were selected according to inclusion criteria. The patients are categorized into two different groups i.e., test group and control group on whom eastern/herbal coded formulation (Dermidoc) and allopathic formulation (PolymixinB-bacitrin) are applied respectively.

## STATISTICAL ANALYSIS

All the data obtained from Sharafi Goth Naik Muhammad dispensary Karachi, was subjected to statistical analysis (SPSS version 22.0), we use sample paired t-test to determine the level of significance of case control study.

## RESULTS

AD is considered by positive clinical sign and symptoms dryness (ichthyosis), Lichenification (leathery), Excoriation (Scratched), Oozing/Crusting, Oedema

**Table 3:** Comparative data between Dermidoc ointment and PolymixinB-bacitrin ointment (Erythema)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	P value
Dermidoc	8(16%)	5(10%)	21(42%)	16(32%)	.013
PolymixinB-bacitrin	6(12%)	8(16%)	20(40%)	16(32%)	

**Table 4:** Comparative data between Dermidoc ointment and PolymixinB-bacitrin ointment (Edema)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	P value
Dermidoc	10(20%)	5(10%)	22(44%)	13(26%)	.007
PolymixinB-bacitrin	6(12%)	15(30%)	12(24%)	17(34%)	

**Table 5:** Comparative data between Dermidoc cream and PolymixinB-bacitrin ointment (Oozing)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	P value
Dermidoc	9(18%)	6(12%)	22(44%)	13(26%)	.015
PolymixinB-bacitrin	7(14%)	6(12%)	20(40%)	17(34%)	

(Swelling), Erythema (Redness) and histopathological changes. AD is utmost common skin inflammatory disorder, which leads to long term inflammation and redness of the skin. There are different systems of medicine for the AD treatment, such as Allopathic, Homeopathic, Unani, Ayurvedic, Chinese etc. In allopathic therapy, different systemic and topical corticosteroids drugs are used for AD treatments. Conventional treatment is more costly so low socioeconomic patients cannot afford it and these therapies also have different hazards or side effects. Unani system of medicine is a traditional system of medicine having many well-known effective and cost saving treatments for AD without any major side effect. Therefore a natural treatment for AD is given below. One of the main aims of this study is to compare the effects of both drugs (control and test) on AD. The clinical effects of this therapy is conducted on 100 subjects which were diagnosed patients of AD at Sharafi Goth Naik Muhammad dispensary. Study design is shown in table 1 and ingredients of test and control drug are shown in table 2.

#### **Clinical response**

Restricted diet was advice and physical examination was carried out before, during and after treatment. The clinical response of the drug was made on the basis of improvement in the patient's signs and symptoms i.e., (Complete improvement, moderate improvement, mild improvement and no improvement).

#### **Erythema (redness)**

Erythema complains has been recorded in both test and control group patients. Patients presenting with complaint of erythema observed complete improvement in 16% of patients, moderate improvement in 10% of patients, mild

improvement in 42% of patients and 32% of patients did not improve with Dermidoc cream. The effects of PolymixinB-bacitrin cream only 12% of the patient indicated complete improvement, 16% shows moderate improvement, 40% shows mild improvement and 32% of patients did not improve. The overall effects of Dermidoccream were better than PolymixinB-bacitrin cream as shown in table 3.

#### **Oedema (swelling)**

Oedema complains has been recorded in both test and control group patients. Patients presenting with complaint of oedema observed complete improvement in 20% of patients, moderate improvement in 10% of patients, mild improvement in 44% of patients and 26% of patients did not improve with Dermidoc cream. The effects of PolymixinB-bacitrin cream only 12% of the patient indicated complete improvement, 30% shows moderate improvement, 24% shows mild improvement and 34% of patients did not improve. The overall effects of Dermidoccream were better than PolymixinB-bacitrin cream as shown in table 4.

#### **Oozing/crusting**

Oozing complains has been recorded in both test and control group patients. Patients presenting with complaint of oozing observed complete improvement in 18% of patients, moderate improvement in 12% of patients, mild improvement in 44% of patients and 26% of patients did not improve with Dermidoc cream. The effects of PolymixinB-bacitrin cream only 14% of the patient indicated complete improvement, 12% shows moderate improvement, 40% shows mild improvement and 34% of patients did not improve. The overall effects of Dermidoccream were better than PolymixinB-bacitrin cream as shown in table 5.

**Table 6:** Comparative data between Dermidoc ointment and PolymixinB-bacitrin ointment (Excoriation)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	P value
Dermidoc	7(14%)	15(30%)	11(22%)	17(34%)	.019
PolymixinB-bacitrin	4(8%)	12(24%)	16(32%)	18(36%)	

**Table 7:** Comparative data between Dermidoc cream and PolymixinB-bacitrin ointment (Lichenification)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	P value
Dermidoc	16(32%)	7(14%)	12(24%)	15(30%)	.012
PolymixinB-bacitrin	5(10%)	6(12%)	19(38%)	20(40%)	

**Table 8:** Comparative data between Dermidoc and PolymixinB-bacitrin (Dryness)

Level of Improvement	Complete improved	Moderate improved	Mild improved	No improved	P value
Dermidoc	13(23%)	10(20%)	12(24%)	15(30%)	.017
PolymixinB-bacitrin	5(10%)	6(12%)	21(42%)	18(36%)	

**Excoriation (scratched)**

Excoriation complains has been recorded in both test and control group patients. Patients presenting with complaint of excoriation observed complete improvement in 14% of patients, moderate improvement in 30% of patients, mild improvement in 22% of patients and 34% of patients did not improve with Dermidoc cream. The effects of PolymixinB-bacitrin cream only 8% of the patient indicated complete improvement, 24% shows moderate improvement, 32% shows mild improvement and 36% of patients did not improve. The overall effects of Dermidoc cream were better than PolymixinB-bacitrin cream as shown in table 6.

**Lichenification (leathery)**

Lichenification complains has been recorded in both test and control group patients. Patients presenting with complaint of lichenification observed complete improvement in 32% of patients, moderate improvement in 14% of patients, mild improvement in 24% of patients and 30% of patients did not improve with Dermidoc cream. The effects of PolymixinB-bacitrin cream only 10% of the patient indicated complete improvement, 12% shows moderate improvement, 38% shows mild improvement and 40% of patients did not improve. The overall effects of Dermidoccream were better than PolymixinB-bacitrin cream as shown in table 7.

**Dryness (ichthyosis)**

Dryness complains has been recorded in both test and control group patients. Patients presenting with complaint of dryness observed complete improvement in 23% of patients, moderate improvement in 20% of patients, mild improvement in 24% of patients and 30% of patients did not improve with Dermidoc cream. The effects of PolymixinB-bacitrin cream only 10% of the patient

indicated complete improvement, 12% shows moderate improvement, 42% shows mild improvement and 36% of patients did not improve. The overall effects of Dermidoccream were better than PolymixinB-bacitrin cream as shown in table 8.

**DISCUSSION**

It is stated that AD belongs to most prevalent skin diseases both in children and infants. It is stated that most of the parents prefer to use non-steroidal therapy for the treatment of symptoms associated with AD to their children (Hon *et al.*, 2006; Kojima *et al.*, 2013). It is suggested that emollient therapy should be applied locally to treat AD, however it has main been common that to control flare-ups and to acquire instant relief, corticosteroids are very often used (Eichenfield *et al.*, 2014; Hanifin *et al.*, 2004). Mostly the parents are unwilling to use topical steroid since the children do not complete their recommended time period for their treatment (Hon *et al.*, 2006; Kojima *et al.*, 2013). This study shows that herbal medicine Dermidoc is effective in the treatment of AD when compare with the PolymixinB-bacitrin. The level of significance between both treatments is compare with paired sample t-test and Dermidoc group shows high significance than PolymixinB-bacitrin group. Consequently, here is necessity of herbal topical skin cream that is safe and effective to treat this disorder. It has been observed that herbal drug Dermidoc proven as well tolerated and has shown better efficacy without any side effects. None of the patient obsoletes the clinical trials due to any of adverse events or for any other reason. Recent studies accompanied on adults also proven that these type of products can potentially improve the skin barrier and symptoms associated with AD, as evidenced using body

cream exert some side effects on prolong use and their efficacy were proven in specific age groups (Weber *et al.*, 2014). Dermidoc cream has proven its efficacy in age group 2 years to patients above than 40 years. Although it is not studied in infant and younger children but this product may provide an effective herbal treatment for AD in all age groups.

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