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Studies on Anti-eczema Activity of Esabdamini

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Abstract

Eczema, an inflammatory condition of the skin, is medically treated with the help of topical steroidal creams, avoidance of known allergens, and the administration of immuno-modulators in severe cases. Aim of the present study was to examine the safety of Esabdamini an topical, herbomineral formulation for the relief of mild to moderate eczema. After confirmation of diagnosis, patients meeting the inclusion and exclusion criteria were included in the study and received Esabdamini Ointment to be applied over the affected area/s thrice daily as a thin film and rubbed in gently and completely for 8 weeks. The efficacy was evaluated on the basis of parameters of modified eczema area and the investigator's global assessment (IGA) on efficacy and tolerability.

Esabdamini ointment was well tolerated and did not lead to any abnormalities in the investigations as compared to the baseline values. The investigators global assessment on the eczema treatment showed that 70 % of patients showed a good improvement while another 30% showed fair improvement in their condition by the end of 8 weeks of treatment. Similarly, the patients' global assessment indicated very good to good response in 50% of the patients at the end of treatment. The efficacy of the developed formulation Esabdamini was found to be very effective without side effects during and after the study and more exploration is required for more effective treatment on large scale. In conclusion, this study confirms the efficacy and safety of Esabdamini Ointment in mild to moderate eczema patients.

Key words:- Esabdamini, Eczema and efficacy clinical effectiveness.

Introduction

Eczema is an inflammatory response of the skin to multiple agents. Eczema can be described as a primary, continuous defect of epidermal differentiation and functions in the presence of sub clinical inflammation-induced skin damage in combination with a further impairment of the skin barrier during the active phase of the disease. Its prevalence varies from 2-3%. Eczematous diseases affect more than 10% of the general population and 15-25% of all dermatological patients suffer from eczema. **[1,2]** The current management of eczema revolves around the use of topical and systemic steroids, antihistamines and soothing and moisturizing agents. Use of steroids (topical and systemic) is fraught with side-effects. . **[1,2]** Antihistamines have practically very little to offer in eczema.

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Similarly, soothing and moisturizing agents can only offer temporary relief **[3].** Medicinal plants are commonly used in traditional medicine for treating and preventing ailments and diseases and are generally considered as health care resource. **[4]** Since the therapy for eczema has limitations in modern medicine, herbal remedies can offer an alternative therapy for eczema. The purpose of this study was to asses the clinical effectiveness of Esabdamini a herbomineral anti-eczema preparation in human subjects.

MATERIALS AND METHODS

Esabdamini:- Individual minerals and herbal extracts were triturated separately in glass mortar and pestle, sifted those powders through 60 #, 80# and 120# sieves. Fine powders thus obtained were mixed together in equal proportion. Conical blender was used for homogenization of the powder mass. Required quantity of the powder was weighed and incorporated into oily

bases to develop Esabdamini ointment. It was coded as F1 (Active ingredients). The formula is summarized in (Table no. 1) This was an open labeled study of Esabdamini ointment in 10 sequential patients of either sex between 18 to 55 years of age suffering from mild to moderate eczema.

Inclusion cr iteria:- Patients who attended OPD and were willing to participate and give written informed consent were enrolled in the study. Patients were followed-up for a period of 6- 8 weeks. Ambulatory patients of both sexes freshly diagnosed as well as pre-existing patients (with a wash out interval of 2 weeks if on treatment) with eczema and clinical diagnosis of eczema in any location of the body were included. The patients had clinical symptoms associated with eczema such as itching, oozing and desquamation.

Exclusion c riteria:- The exclusion criteria included patients with infected lesions, history of ischemic heart disease, pregnant and lactating women; patients receiving corticosteroid treatment; patients with history of gastritis, peptic ulcer, bleeding ulcers; HIV, HBV and known allergic reaction to systemic/topical study drugs.

Experimental protocol:- After confirmation of diagnosis, patients meeting the inclusion and exclusion criteria were included in the study and received Esabdamini Ointment to be applied over the affected area/s thrice daily as a thin film and rubbed in gently and completely for 8 weeks. Patients could be withdrawn from the study at their own request or if they experienced intolerable adverse events, showed insufficient therapeutic effect, or needed deviations from the protocol at the discretion of the investigator. Safety and efficacy evaluation of patients' clinical response to treatment was monitored from screening (day 0) till the end of therapy (end of 8 weeks). All data were carefully Recorded. Side effects were closely monitored in all patients. All adverse events were recorded by the investigator, and rated for severity and relationship to the study medication. However, significant exacerbations or worsening of pre-existing conditions were recorded. The efficacy was evaluated on the basis of parameters of modified eczema area like Itching, Discharge ,Burning sensation, Macules , Papules, Vesicles , Papulo-vesicles, Scaling , Lichencification , Hyper pigmentation, Excoriation , Tenderness, Erythema , Oedema and Crusting In addition the investigator's global assessment (IGA) on efficacy and tolerability was performed on a scale of 1-5, namely Very Good = 5, Good = 4, Fair = 3, Poor = 2 and Very Poor = 1. Patient's global assessment on the efficacy and tolerability of treatment was similarly performed.

The observations and the data collected were tabulated and stastically analyzed by applying Z-test for proportion. **[5]**

Results

Of the 15 patients enrolled in the study, 5 of them lost to follow-up while 10 completed the study with reduction in symptoms of eczema to varying degrees. The demographic characteristics of the study are given in Table 2 and 3. The observations before, during and after the treatment were recorded and have been tabulated. Treatment with the Esabdamini ointment was well tolerated and did not lead to any abnormalities in the investigations as compared to the baseline values. Patients tolerated the treatment without any major adverse events that needed discontinuation.

Table No. I Anti-eczema: Esabdamini (Composition and concentration)

Sr. No.	Botanical/Chemical name	Common name	Concentration	Formula for ointment (30g)
1	Pb_2O_3	Shendur	0.375 gm-25%	F1= 1.5g
2	*Cinnamomum camphora,* linn (Lauraceae)	Kapur	0.375 gm-25%	
3	*Uncaria gambier,* Roxb (Rubiaceae)	Kattha / Pale catechu	0.375 gm-25%	
4	Lead oxide	Muddarshing (Litharge)	0.375 gm-25%	
Formula for Esabdamini				
Sr.No.	**Ingredients**	**Quantity taken**	**Properties**	
1.	F_1 (Active Ingredients)	1.5 gm	Active potent ingredient	
2.	Bees wax	0.6 gm	Oily base	
3.	Cetostearyl alcohol	0.9 gm	Oily base	
4.	Wool fat	1.5 gm	Oily base	
5.	White soft paraffin	25.5 gm	Oily base	

Table 2 Demographic characteristic of patients

	Number of patients (n =10)	Age (years)
Male	8	31.25 ± 2.194 (20-47)
Female	2	29.50 ± 2.50 (28-32)
Mean	10	30.90 ± 1.785 (20-47)

Table 3 Adverse events observed before the treatment with Esabdamini therapy.

Adverse events	Number of patients (n=10)	(%)
Epigastric pain	2	20
Nausea	3	30
Vomiting	3	30
Headache	4	40
Total	10	

Table 4 Effect of Esabdamini on the Itching, Discharge, Burning sensation, Macules, Papules, Vesicles and Papulo-vesicles.

Clinical features	0 day	1 week		2 weeks		3 weeks		4 weeks		6 weeks		8 weeks		10 weeks	
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Itching	10	10	0	8	20	6	40	5	50	4	60	3	70	2	80
Discharge	7	7	0	6	14.28	5	28.571	4	42.857	3	57.14	3	57.14	2	71.428
Burning sensation	6	6	0	6	0	5	16.67	4	33.34	3	50	2	66.66	1	83.34
Macules	8	8	0	7	12.5	7	12.5	6	25	5	37.50	3	62.50	2	75
Papules	6	6	0	5	16.67	5	16.67	4	33.34	3	50	2	66.66	1	83.34
Vesicles	5	5	0	4	20	4	20	3	40	2	60	2	60	1	80
Papulo-vesicles	5	5	0	4	20	4	20	3	40	2	60	2	60	1	80

N= Number of patients; %= percentage improvement

Table 5 effect of Esabdamini on the Scaling Lichenification Hyper pigmentation Excoriation Tenderness

Clinical features	0 day	1 week		2 weeks		3 weeks		4 weeks		6 weeks		8 weeks		10 weeks	
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Scaling	5	5	0	4	20	3	40	3	40	2	60	2	60	1	80
Lichencification	6	6	0	5	16.67	4	33.34	4	33.34	3	50	2	66.66	2	66.66
Hyper pigmentation	5	5	0	5	0	4	20	4	20	3	40	3	40	3	40
Excoriation	4	4	0	3	25	3	25	3	25	2	50	2	50	1	75
Tenderness	8	8	0	7	12.5	6	25	5	37.50	5	37.50	4	50	2	75

Table 6 effect of Esabdamini on the Erythema, Oedema and Crusting

Clinical features	0 day	1 week		2 weeks		3 weeks		4 weeks		6 weeks		8 weeks		10 weeks	
	N	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Erythema	6	6	0	5	16.67	4	33.34	3	50	3	50	2	66.66	1	83.34
Oedema	6	6	0	5	16.67	5	33.34	4	50	4	50	2	66.66	1	83.34
Crusting	7	7	0	6	14.28	5	28.571	4	42.857	3	57.14	2	71.42	1	85.714

Table 7 The investigator's global assessment (IGA) on the efficacy and tolerability on treatment with Esabdamini

Scale /assessment	Efficacy	Tolerability
Very Good = 5	1	9
Good = 4	7	1
Fair = 3	3	-
Poor = 2	-	-
Very Poor = 1	-	-

Table 8 Patients' global assessment on the efficacy and tolerability on treatment with Esabdamini

Scale /assessment	Efficacy	Tolerability
Very Good = 5	3	6
Good = 4	5	2
Fair = 3	2	1
Poor = 2	-	1
Very Poor = 1	-	-

The effect of Esabdamini on the Itching, Discharge and Burning sensation after 10 weeks of treatment was found to be 80% (Z=0.03271, P<0.05), 71.428% (Z=0.17892, P<0.05) and 83.34% (Z=0.428404, P<0.05) respectively. Table 4. It was observed that after treatment improvement in Macules, Papules, Vesicles and Papulo-vesicles was found to be 75% (Z=0.013976, P<0.05), 83.34% (Z=0.50, P<0.05), 80% (Z=0.9230, P<0.05) and 80% (Z=0.153992, P<0.05). Table 4. It was also evident that improvement in Scaling, Lichencification, Hyper pigmentation, Excoriation and Tenderness was found to 80 % (Z=0.955222, P<0.05); 66.66% (Z=0.50, P<0.05); 40% (Z=0.623237, P<0.05); 75% (Z=0.999682, P<0.05) and 75% (Z=0.013047, P<0.05), after the 10 weeks of treatment. Table 5. The effect of Esabdamini on the Erythema, Oedema and Crusting at the end of treatment was found to be 83.34% (Z=0.650223, P<0.05); 83.34% (Z=0.42247, P<0.05) and 85.714% (Z=0.319706, P<0.05) Table 6.

The investigators global assessment on the eczema treatment showed that 70 % of patients showed a good improvement while another 30% showed fair improvement in their condition by the end of 8 weeks of treatment. Table 7. Similarly, the patients' global assessment indicated very good to good response in 50% of the patients at the end of treatment. Table 8.

Discussion

Disturbances in skin function is a major etiological factor in eczema. The disease is characterized by intense pruritus and scratching in combination with cutaneous hyperreactivity and reduced threshold for pruritus. Further, the lipid composition of the stratum

corneum of the epidermis is also damaged in eczema. This leads to dryness of the skin and a higher permeability to allergens and irritants. **[6]** Considering the multifactorial etiology of eczema, it is only logical to expect an encouraging response in this trial to the herbal formulation. This formulation contains herbal and mineral ingredients that counteract several pathological mechanisms, Now a days, dermal formulations are prepared along with the herbal extracts and combinations with minerals the parameters for the formulations differ depending upon the dosage form.

Generally cream or ointment are prepared to have prolonged contact with skin surface ph of the formulation must be within the range 4 to 6. **[7& 8]** In the present study the ingredients selected from herbal sources include Kattha (*Uncaria gambier*, linn) water extract which is astringent action with tannins contributing major chemical components part. It helps in absorption of exudations from the affected area and develop dryness. Shendur (Pb_2O_3) avoids entry of micro-organisms from different sources. **[9 & 10]** While the Litharge (Lead oxide) has similar function like shendur. Multiple complications are thus avoided with the help of these minerals. Kapur (*Cinnamomum camphora* linn) is another ingredient from herbal source which already has been proved for its antibacterial and antiviral potential. Hence it is incorporated in most of the herbal as well as herbomineral market formulations. **[9 10 & 11]** As previously by Ali et al reported the clinical significance of Kapur and Litharge in unani herbal formulation for treatment of dermal diseases.**[12]** Oily base help in keeping the formulation on the surface for longer duration also it helps to cross the lipoproteinous barriers in tissues and cells. Components in the formulations reach at the infected site. Some of them restrict the unwanted behavior of the tissues and some help in rejuvenation as well as to restore the function.

The efficacy of the developed formulation Esabdamini was found to be very effective without side effects during and after the study and more exploration is required for more effective treatment on large scale. In conclusion, this study confirms the efficacy and safety of Esabdamini Ointment in mild to moderate eczema patients.

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