Clinical Evaluation of the Effect of *Wrightia tinctoria* Formulation in the Management of Eczema

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This article presents the clinical findings of a controlled clinical study undertaken to evaluate the safety and efficacy of a topical herbal formulation based on combined extracts of *Wrightia tinctoria*, *Salix* L., *Tragia involucrata* L., and *Cocos nucifera* in the treatment of eczema lesions as compared with treatment with an allopathy control (hydrocortisone 1% ointment). Thirty patients suffering from chronic inflammatory eczema without any systemic complications were enrolled in a clinical study and were divided randomly into 2 equal groups. Group 1 was treated with the herbal formulation, and group 2 was treated with an allopathy control formulation of hydrocortisone 1% ointment twice daily. Each patient received treatment for 8 weeks and visited the clinic a minimum of 6 times, at baseline and at weeks 1, 2, 4, 6, and 8. Hemogram, liver function, and renal function testing of blood samples taken at the beginning and end of treatment for each subject suggest no systemic toxic effects with either the herbal formulation or the hydrocortisone 1% ointment treatment control formulation. Examination of photographs taken before and after treatment revealed significant regression of eczema with the use of the herbal formulation. The treatment sites were scored at each visit by an expert dermatologist for erythema, pustules, oozing, and itching to determine the efficacy of treatment with the herbal formulation as compared with the hydrocortisone 1% ointment control formulation.

Itching and oozing were found to be statistically significantly reduced with time ($P<.5$) with both formulations. With the herbal formulation, erythema and pustules were found to be statistically significantly reduced with time ($P=.005$ for erythema; $P=.016$ for pustules) during the 8-week treatment period. No statistically significant reduction in erythema and pustule scores were observed with time ($P=070$ for erythema; $P=.294$ for itching) with the hydrocortisone 1% ointment control formulation suggesting statistically significantly superior efficacy with the herbal formulation as compared with the hydrocortisone 1% ointment control formulation.

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With the changing environment, food habits, and lifestyle, incidences of chronic inflammatory skin disorders like eczema are on the rise. In any skin clinic, patients with chronic inflammatory disorders presenting with symptoms of eczema will represent approximately 40% of the cases. Prevalence varies among countries, ranging from 25 to 75 cases per 1000 of the population. In the United States alone, the National Institutes of Health estimate that 31.6 million people have some form of eczema.[1]

Histologically, dermal vessel changes are marked in all stages of the disease: vascular dilation and lymphohistiocytic proliferation. In the acute oozing stage, spongiosis is predominant. In the subacute moist stage, spongiosis is less evident and acanthosis is more predominant. In the chronic thickened stage, acanthosis is predominant with varying degrees of lymphohistiocytic proliferation. Common symptoms observed with eczema may include 1 or more of the following: erythema, pain, pustules, skin edema, itching, and dryness, with possible crusting, flaking, blistering, cracking, oozing, or bleeding at the disease site.[2]

There are numerous therapies in the field of allopathy medicine[3,4] for eczema. The treatments have been researched and developed to regress 1 or more symptoms of itching, erythema, pustules, pain, and oozing. However, most of these therapies provide only temporary symptomatic relief and are either unsatisfactory or very expensive.[5,6] The therapies are associated with either short-term or long-term undesired side effect profiles.

Herbal formulations, in general, are less expensive and are well known to minimize the risks for undesired side effects. Several herbal formulations are in clinical use in the Indian system of traditional medicine to treat skin diseases.[7-10] This article presents the results of evaluation in a controlled clinical study of an herbal formulation containing *Wrightia tinctoria*, *Salix* L., *Tragia involucrata* L., and *Cocos nucifera* in the management of eczema as compared with treatment with an allopathy control of hydrocortisone 1% ointment.

STUDY MATERIALS AND METHOD

The clinical study was organized and conducted under an institutional review board–approved protocol as per Good Clinical Practice guidelines. Thirty male and female adult patients with chronic inflammatory eczema were voluntarily recruited as per the inclusion and exclusion criteria defined in the study protocol approved by the ethical committee. Thirty patients were enrolled in the clinical study and were randomly assigned to 2 groups of 15 each. On treatment-initiation day, each subject was assigned a discrete sequential number on a first-come, first-served basis and assigned to the treatment group by a computer-generated randomization table. Group 1 was treated with an herbal formulation containing extracts of *W tinctoria*, *Salix* L., *T involucrata* L., and *C nucifera* twice daily. Group 2 was also treated twice daily with an allopathy control formulation of hydrocortisone 1% ointment. All patients recruited were screened and determined to be suffering from chronic inflammatory eczema without any systemic complications.

TABLE 1

Statistical Analysis of Measurements for Erythema

Time Point, wk	Group 1 (Herbal) (n=15)		Group 2 (HC 1% Ointment Control)(n=15)		Between-Treatment Effects	
	Mean	SD	Mean	SD	*t* Statistic	*P*
Baseline	0.56	0.63	0.40	0.51	1.09	.360
1	0.64	0.63	0.42	0.51	0.59	.624
2	0.14	0.36	0.55	0.52	1.92	.140
4	0.00	0.00	0.00	0.00	2.44	.088
6	0.10	0.32	0.22	0.44	0.97	.416
8	0.22	0.44	0.10	0.32	0.77	.517
F statistic	3.73		2.17			
P	.005		.070			

Abbreviations: HC, hydrocortisone; SD, standard deviation.

TABLE 2

Statistical Analysis of Measurements for Pustules

Time Point, wk	Group 1 (Herbal) (n=15)		Group 2 (HC 1% Ointment Control)(n=15)		Between-Treatment Effects	
	Mean	SD	Mean	SD	*t* Statistic	*P*
Baseline	1.06	0.77	0.93	0.88	0.40	.752
1	0.86	0.66	0.67	0.89	0.45	.722
2	0.40	0.63	0.64	0.67	0.78	.512
4	0.89	0.60	0.22	0.67	1.72	.186
6	0.36	0.50	0.50	0.71	0.08	.969
8	0.36	0.67	0.36	0.67	0.05	.987
F statistic	3.03		1.26			
P	.016		.294			

Abbreviations: HC, hydrocortisone; SD, standard deviation.

The treatment period was 8 weeks for each patient. Each subject visited the clinic 6 times, at baseline and at weeks 1, 2, 4, 6, and 8 during the treatment period. Safety of the herbal formulation was assessed by monitoring vital signs (temperature, systolic and diastolic blood pressure, pulse, and respiratory rate) during every treatment visit. Hemogram testing (total leukocyte counts, differential polymorphonuclear neutrophil count, differential lymphocytes count, differential eosinophils count, and hemoglobin); liver function testing (serium glutamic oxaloacetic transaminase, serum glutamic pyruvic transaminase, and serum bilirubin); and renal function testing (serum creatinine, serum urea) measurements were also taken for each patient at the beginning and end of the study. Adverse events, if any, were recorded.

Efficacy of the herbal formulation was assessed by scoring erythema, pustules, oozing, and itching during every clinical visit. Photographs of the treatment site were also taken at the beginning and end of treatment for each subject.

RESULTS AND DISCUSSION

Safety Assessment

There were no serious adverse events reported in the study. Data on vital signs and blood examination (liver function test, renal function test, and hemogram test) monitored during the study period were analyzed statistically using regular 1-way analysis of variance, repeated measures analysis of variance, and paired *t* test (whichever applicable). There were no statistically significant changes ($P>.05$) with the different safety parameters assayed over the study period in both groups. The data clearly suggest that the herbal formulation is not toxic to the liver, kidneys, or hemopoietic system.

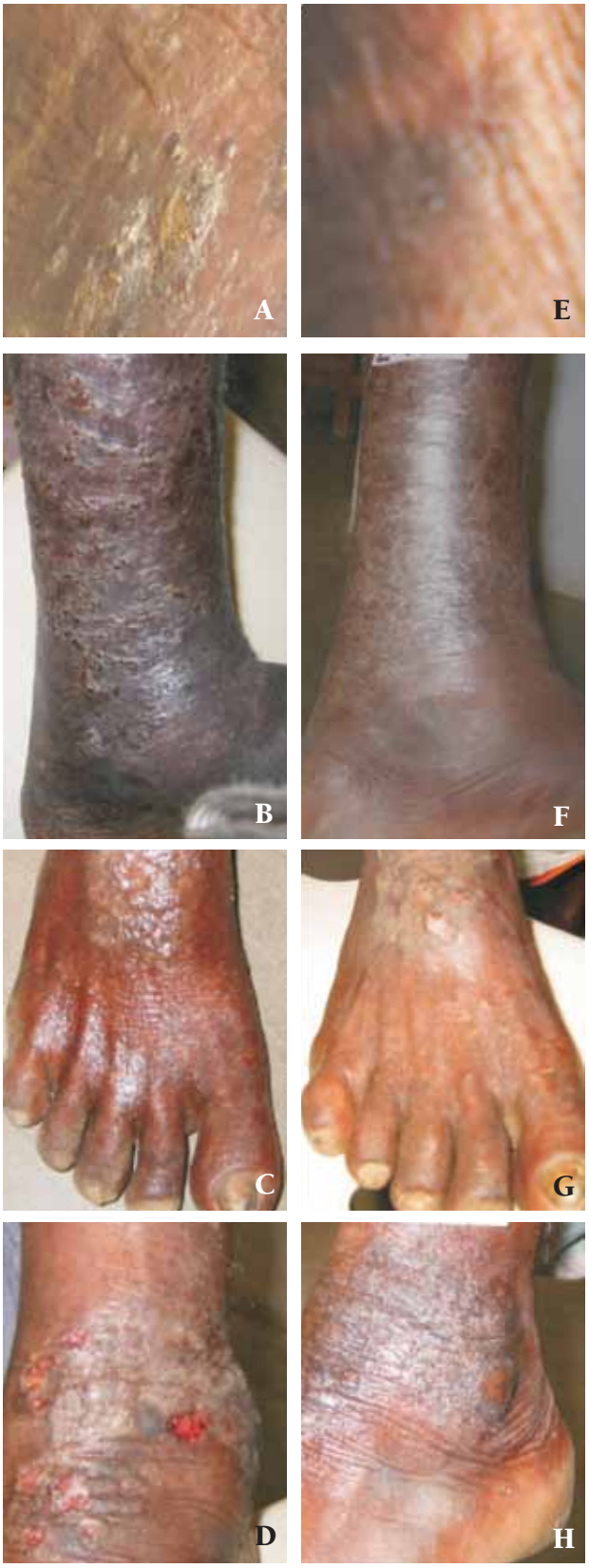
Efficacy Assessment

An expert dermatologist assessed the efficacy of the herbal formulation at each clinical visit by scoring erythema, pustules, oozing, and itching. Photographs of the treatment site were also taken at the beginning and end of treatment for each subject. Visually significant resolution of the lesions was observed with the herbal treatment in 8 weeks (Figure 1).

Erythema was evaluated at each visit and scored using the Draize scale,[11] where 0=none; 1=very slight; 2=well defined; 3=moderate; and 4=severe. Erythema decreased with time for both treatment groups (Table 1). However, the reduction in erythema was only statistically significant with the herbal treatment ($P=.005$) as compared with the hydrocortisone 1% ointment treatment ($P=.070$).

Pustule measurements were performed at every visit and scored as follows: 0=none, no pustules in the lesion; 1=mild, few pustules in the lesion; 2=moderate, pustules partially covering the lesion; 3=severe, pustules covering the whole lesion. The pustules decreased with time for both treatment groups (Table 2). However, the reduction in pustules was only statistically significant with the herbal treatment ($P=.016$) as compared with the hydrocortisone 1% ointment treatment ($P=.294$).

The statistical data analysis clearly indicates that the herbal formulation for the regression of pustules in the treatment of eczema is very effective and is superior to the hydrocortisone 1% ointment control formulation.



Patients with eczema before (A, B, C, D) and after 8 weeks of treatment with an herbal formulation containing *Wrightia tinctoria, Salix* L., *Tragia involucrata* L., *and Cocos nucifera* (E, F, G, H).

Oozing measurements were performed at every visit and scored as follows: 0=none, no oozing from the lesion; 1=mild, mild oozing from the lesion; 2=moderate, moderate oozing from the lesion; and 3=severe, abundant oozing. The oozing decreased with time for both treatment groups and was found to be statistically significant ($P=.023$ for the herbal treatment and $P=.002$ for the hydrocortisone 1% ointment treatment)(Table 3).

The statistical data analysis clearly indicates that the herbal formulation for the regression of oozing in the treatment of eczema is very effective and is comparable with the hydrocortisone 1% ointment control formulation.

Itching was scored by the patients at every visit and documented. The intensity of the itching at the treatment site was scored on a visual analog scale of 0 to 100 mm, where 0=no itching and 100 mm=intolerable itching. The more itching experienced by the patient, the higher the itching score. Statistically significant reduction in itching with time was observed with both treatment groups ($P<.05$)(Table 4).

The statistical data analysis clearly indicates that the herbal formulation for the regression of itching in the treatment of eczema is very effective and is comparable with the hydrocortisone 1% ointment control formulation.

SUMMARY

The herbal formulation containing *W tinctoria*, *Salix* L., *T involucrata* L., and *C nucifera* evaluated in this study for the management of patients with chronic eczema was found to be safe and nontoxic to the liver, kidneys, and hemopoietic system.

Photographs of the treatment site at the beginning and end of treatment clearly show significant resolution of the eczema lesions at the application site with the application of the herbal formulation during the course of 8 weeks.

Efficacy of the herbal formulation was assessed by scoring erythema, pustules, oozing, and itching during each clinical visit.

Erythema and pustules decreased with time for both treatment groups. However, the reduction in erythema and pustules was only statistically significant with the herbal treatment ($P=.005$ for erythema; $P=.016$ for pustules) as compared with the hydrocortisone 1% ointment treatment ($P=.070$ for erythema; $P=.294$ for pustules). The statistical data analysis clearly indicates that the herbal formulation for the regression of erythema and pustules in the treatment of eczema is very effective and is superior to the hydrocortisone 1% ointment control formulation.

Statistically significant reduction in oozing (Table 3) and itching (Table 4) with time was observed with both treatment groups ($P<.05$). The statistical data analysis clearly indicates that the herbal formulation for the regression of itching and oozing in the treatment

Table 3
Statistical Analysis of Measurements for Oozing

Time Point, wk	Group 1 (Herbal) (n=15)		Group 2 (HC 1% Ointment Control)(n=15)		Between-Treatment Effects	
	Mean	SD	Mean	SD	*t* Statistic	*P*
Baseline	1.00	0.73	1.20	0.94	0.40	.752
1	0.93	0.62	0.67	0.78	0.50	.684
2	0.40	0.63	0.55	0.52	1.26	.300
4	0.89	0.60	0.11	0.33	2.97	.050
6	0.36	0.50	0.40	0.52	0.51	.681
8	0.45	0.69	0.27	0.47	0.64	.594
F statistic	2.80		4.19			
P	.023		.002			

Abbreviations: HC, hydrocortisone; SD, standard deviation.

Table 4
Statistical Analysis of Measurements for Itching

Time Point, wk	Group 1 (Herbal) (n=15)		Group 2 (HC 1% Ointment Control)(n=15)		Between-Treatment Effects	
	Mean	SD	Mean	SD	*t* Statistic	*P*
Baseline	51	11.31	49	11.29	2.04	.118
1	45	12.87	45	10.07	1.15	.340
2	32	14.46	48	18.14	3.00	.040
4	39	4.92	23	13.61	3.48	.029
6	20	17.68	31	20.60	0.57	.640
8	16	12.39	19	18.63	0.07	.977
F statistic	14.17		8.30			
P	.0001		.0001			

Abbreviations: HC, hydrocortisone; SD, standard deviation.

of eczema is very effective and is comparable with the hydrocortisone 1% ointment control formulation.

It is clear from the photographs, clinical examination, and statistical analysis of the clinical data that the herbal formulation containing extracts of *W tinctoria*, *Salix* L., *T involucrata* L., and *C nucifera* is very effective in regression of eczema. In addition, evaluation of vital signs, hemogram, liver function test, and renal function test results show that the herbal formulation is also very safe to use on humans. Affordability, effectiveness, and absence of side effects will provide an attractive alternative therapy for the management of eczema. Although it is true in the study that the herbal formulation produced better results than hydrocortisone 1% ointment, it is important to note that practitioners of allopathic medicine would likely use much stronger products than hydrocortisone 1% ointment.

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