STUDIES ON SUDANESE MEDICINAL PLANTS. II. EVALUATION OF AN EXTRACT OF *LUPINUS TERMIS* SEEDS IN CHRONIC ECZEMA

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ABSTRACT.—A double-blind clinical trial comparing a 10% ointment prepared from a 95% ethanol extract of *Lupinus termis* seeds with a 0.02% flumethasone pivalate ointment and a placebo showed that the *Lupinus termis* extractive was effective in the treatment of chronic eczema. The results obtained with the extract were statistically comparable to those obtained with the corticoid therapy.

In an earlier publication (1), we reported the results of an open clinical trial to test the effectiveness of an extract of *Lupinus termis* seeds in the management of chronic hand and foot eczema. Before proceeding further with the isolation of the principle(s) responsible for the pharmacological activity of this plant, it was deemed necessary to further confirm the results in a double-blind clinical trial.

RESULTS AND DISCUSSION

Twenty-four patients suffering from chronic eczema were selected and given the extract of *L. termis* seeds in an ointment form, a placebo (White Soft Paraffin B.P.) or Locacorten® Ointment as a standard therapy (tables 1, 2, 3).

White Soft Paraffin B.P. was chosen as a placebo to eliminate any bias which may be due to an improvement in the patient's condition resulting from the emollient effect of the ointment base. Locacorten® Ointment, which contains as active substance a synthetic corticoid ester and which is often used in the treatment of this condition, was considered to be a suitable standard for rating the activity of the plant extract.

Evaluation of the treatment was according to whether or not an improvement was observed in the symptoms of the disease namely, erythema, pruritus, scaling, infiltrate, crusts and/or fissures. Each symptom was assigned a number (0 = absent, 1 = slight, 2 = present, 3 = severe) and the overall evaluation of each case was a total assessment of the symptoms at the end of the trial (9 weeks from commencement of treatment or the time of complete resolution of lesions or termination of the trial at the request of the patient). Each patient was then recorded as showing no response (0), a moderate response (1+), a good response (2+), a very good response (3+) if all the clinical symptoms were absent.

Fifty percent of the patients treated with *L. termis* ointment had complete resolution of lesions and 12% showed partial improvement. This further substantiates our earlier finding where 52% of the patients had complete resolution of their lesions and 26% had partial resolution (1).

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TABLE 1. *L. termis* ointment group.[a]

Patient	Type and distribution of chronic eczema	Duration of illness before commencing treatment	Symptoms:	E	P	S	I	C	F[b]	Result of treatment[c]
1. Male 51 years..	Foot. Dorsum of feet round ankle.	2 months	Before treatment:	2	1	1	3	1	0	On 7th week, lesions were completely resolved. [Very good (3+)].
			7th week:	0	0	0	0	0	0	
2. Male 13 years..	Legs.	2½ months	Before treatment:	2	3	3	2	2	0	On 2nd week, eczema exacerbated; severe itching; trial discontinued. [No success (0)].
			2nd week:	3	3	2	3	3	0	
3. Male 17 years..	Foot. Dorsum of both feet.	4 months	Before treatment:	2	3	2	3	0	0	On 9th week, all symptoms disappeared, except for a slight infiltrate. [Good (2+)].
			9th week:	0	0	0	1	0	0	
4. Female 43 years..	Hand and foot.	12 years	Before treatment:	1	1	2	3	0	3	On 6th week, lesions were completely resolved. [Very good (3+)].
			6th week:	0	0	0	0	0	0	
5. Female 24 years..	Foot. Both feet.	2 years	Before treatment:	1	1	1	2	0	3	On 5th week, lesions were completely resolved. [Very good (3+)].
			5th week:	0	0	0	0	0	0	
6. Female 11 years..	Foot.	Several years	Before treatment:	2	3	3	0	0	2	On 7th week, lesions were completely resolved. [Very good (3+)].
			7th week:	0	0	0	0	0	0	
7. Female 17 years..	Foot. Dorsum of feet.	2 years	Before treatment:	2	2	0	3	0	0	On 6th week, patient's condition got worse; trial discontinued. [No success (0)].
			6th week:	3	3	1	2	3	0	
8. Female 19 years..	Foot.	1 year	Before treatment:	2	3	1	3	1	0	On 4th week, patient defaulted; trial stopped. [No success (0)].
			3rd week:	1	2	1	3	0	0	

[a]An analysis of variance (ANOVA) for the drug effect by the groups, sex with age showed that the only significant factor was the drug groups.

Newman-Keuls test for comparison of means of the three groups showed $p<0.01$ for the two drugs *versus* placebo.

[b]Symptoms: Erythema (E), Pruritus (P), Scaling (S), Infiltrate (I), Crusts (C), Fissures (F).

[c]Results were rated as Very good (3+), Good (2+), Moderate (1+), No success (0). The numbers assigned to the ratings were used for statistical evaluation.

In the group treated with Locacorten® Ointment, it was found that 63% of the patients had complete resolution of lesions and 37% showed partial improvement.

The results with *L. termis* ointment and Locacorten® Ointment are statistically comparable and show a significant difference from the placebo. Subjectively, it appears that the corticoid ointment is somewhat better than the extractive at the concentrations used, especially in cases where partial resolution of the

TABLE 2. Placebo group.[a]

Patient	Type and distribution of chronic eczema	Duration of illness before commencing treatment	Symptoms:	E	P	S	I	C	F[b]	Result of treatment[c]
1. Female 17 years	Foot. Both feet.	1 year	Before treatment:	1	2	3	3	0	3	On 9th week, lesions were still unresolved. [No success (0)].
			9th week:	0	2	1	2	0	2	
2. Male 27 years	Foot. Dorsum of left foot and right leg.	2 years	Before treatment:	1	2	1	3	0	0	On 9th week, lesions were still unresolved. [No success (0)].
			9th week:	1	2	0	2	0	0	
3. Male 54 years	Leg.	3 months	Before treatment:	3	3	2	1	2	0	On 4th week, lesions were unresolved; severe itching; trial discontinued. [No success (0)].
			4th week:	2	3	0	1	1	0	
4. Female 18 years	Hand and foot.	3 months	Before treatment:	2	1	1	1	1	0	On 9th week, lesions were unresolved; severe itching. [No success (0)].
			9th week:	2	3	0	1	0	0	
5. Female 18 years	Legs and forearm.	3 months	Before treatment:	2	1	2	1	1	0	On 5th week, lesions were unresolved; patient's condition got worse; trial discontinued. [No success (0)].
			5th week:	3	3	0	1	1	0	
6. Female 12 years	Hand and foot.	5 months	Before treatment:	3	3	3	2	3	3	On 9th week, patient was still complaining of itching, fissures and erythema. [Moderate success (1+)].
			9th week:	2	2	0	1	0	2	
7. Male 18 years	Foot.	5 years	Before treatment:	0	1	2	3	0	0	On 1st week, lesions were still unresolved; patient defaulted. [No success (0)].
			1st week:	0	0	1	2	0	0	
8. Male 15 years	Foot.	5 years	Before treatment:	2	3	2	2	1	0	On 2nd week, the condition got worse; trial discontinued. [No success (0)].
			2nd week:	3	3	1	2	1	0	

[a], [b], [c]Refer to footnotes in table 1.

lesions was observed (tables 1, 3). A much larger population of patients would be needed to provide a definitive answer in this matter.

In the earlier trial, it was found that some patients complained of itching which was improved by administration of an oral antihistamine. Pruritus is a symptom of the disease (tables 1, 2, 3), but the ointment base and the extract may have contributed to its increase (compare table 1 and 2 to table 3). This complication may have contributed to the high rate of defaulting observed earlier.

Further work is in progress to identify the active principle(s) and to assess the efficacy of this plant in other types of eczema and dermatological disorders.

TABLE 3. Locacorten® ointment group.[a]

Patient	Type and distribution of chronic eczema	Duration of illness before commencing treatment	*Symptoms:*	E	P	S	I	C	F[b]	Result of treatment[c]
1. Female 18 years	Foot.	16 years	Before treatment:	3	3	2	3	3	0	On 9th week, scaling and crusts disappeared; erythema, pruritus and infiltrate still present. [Moderate (1+)].
			9th week:	1	1	0	2	0	0	
2. Male 7 years	Leg. Right and left.	1 year	Before treatment:	3	3	3	3	3	0	On 1st week, moderate improvement was observed; then patient defaulted. [Moderate (1+)].
			1st week:	2	1	1	2	1	0	
3. Male 12 years	Leg and forearms.	5 years	Before treatment:	2	3	2	3	3	0	On 7th week, lesions were completely resolved. [Very good (3+)].
			7th week:	0	0	0	0	0	0	
4. Female 22 years	Foot. Right and left.	4 years	Before treatment:	1	3	3	3	1	3	On 9th week, lesions were completely resolved. [Very good (3+)].
			9th week:	0	0	0	0	0	0	
5. Male 7 years	Leg. Left.	2 years	Before treatment:	3	3	2	3	3	0	On 2nd week, lesions were completely resolved. [Very good (3+)].
			2nd week:	0	0	0	0	0	0	
6. Male 65 years	Hand and foot.	3 months	Before treatment:	3	1	2	3	1	3	On 4th week, lesions were completely resolved. [Very good (3+)].
			4th week:	0	0	0	0	0	0	
7. Female 25 years	Leg. Right.	19 years	Before treatment:	2	3	2	3	1	0	On 9th week, pruritus and infiltrate were still present. [Moderate (1+)].
			9th week:	0	1	0	3	0	0	
8. Male 60 years	Foot. Legs and dorsum of feet.	3 years	Before treatment:	3	1	1	3	2	0	On 7th week, lesions were completely resolved. [Very good (3+)].
			7th week:	0	0	0	0	0	0	

[a], [b], [c]Refer to footnotes in table 1.

EXPERIMENTAL

PLANT MATERIAL.—*Lupinus termis* Forsk. (Leguminosae) seeds were obtained from the local market in Khartoum (1).

PREPARATION OF OINTMENTS.—The seeds were powdered as described earlier (1). However, a Soxhlet was not used for extraction. Instead, the 95% ethanol extract was obtained by percolation of the powdered material at room temperature followed by removal of the solvent under vacuum; a 10% w/w red-brown extractive was obtained. To prepare a 10% w/w ointment, the extract was blended with White Soft Paraffin B.P.

Locacorten® Ointment (Ciba) consisted of 0.02% flumethasone pivalate in an ointment base.

The three preparations (*Lupinus termis* ointment, White Soft Paraffin B.P. and Locacorten® Ointment) were dispensed in identical containers which were carefully wrapped and randomly numbered.

SELECTION OF PATIENTS.—As with the previous trial, patients were randomly selected. They had no known history of allergy.

APPLICATION OF OINTMENT.—The patients were advised to apply the ointment as a thin cover morning and evening. No occlusive dressing was used, and no restrictions on diet or cleansing habits were imposed.

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