CLINICAL EVALUATION OF DI-PARALENE IN THE MANAGEMENT OF TINEA CAPITIS*

M. W. ROSENTHAL, M.D., C. W. DAESCHNER, M.D. AND W. J. FAHLBERG, PH.D.*

In previous reports (1, 2) it has been established that several of the antihistaminic drugs possessed varying degrees of fungistatic activity *in vitro*. Di-Paralene (chlorocyclizine hydrochloride) Abbott, appeared to be the most active of this group on the basis of *in vitro* studies and it deemed desirable to evaluate its efficacy in the management of tinea capitis.

In clinical pediatrics practice, tinea capitis represents a relatively common problem that is often difficult to manage. Though causing little physical discomfort to the infected child, it does represent a significant social problem. To the patient's parents and to the attending physician, the diagnosis of tinea capitis usually signifies a protracted period of medical observation and daily home treatment. Miller and his associates (4) have reported that in many instances the fungous infestation of the scalp is extremely resistant to topical therapy and, ultimately, complete epilation of the scalp may have to be performed before a cure can be achieved. Schwartz, et al. (5) have observed that agents which rapidly and dependably eliminate fungous infections of the glabrous skin, may completely fail to influence the course of tinea capitis. Therefore, it was felt that children affected with tinea capitis represented a desirable group for the clinical evaluation of the specific fungistatic activity of Di-Paralene *in vivo*.

MATERIALS AND METHODS

Treatment

Ointments containing two and five percent concentrations of Di-Paralene were prepared for topical application in the standard U.S.P. hydrophilic petrolatum.† As a control gauze patches impregnated with these Di-Paralene preparations were applied for a 48 hour period to the inner surface of the forearm of 197 volunteers. No local reactions were noted following the removal of the patch.

Patients

The patients were selected from routine admissions to the Pediatric Clinic of the Jefferson Davis City-County Hospital, Houston, Texas. The study group consisted of 23 males and 6 females ranging in age from about 2 to 11 years, with a mean age of approximately 6 years. Thirteen patients (45%) had received some type of therapy previously without observable improvement in their clinical status. In the earlier part of this study an attempt was made to select only those patients whose past clinical history suggested refractoriness to therapy, but as the study progressed all well established cases of tinea capitis that presented

* From the Departments of Pediatrics and Microbiology, Baylor University College of Medicine and the Jefferson Davis Hospital, Houston, Texas.

† Abbott.

Received for publication March 26, 1954.

themselves were included in the study group. Case histories revealed that the parents of these patients had recognized the disease for from two to eight weeks prior to the time of their first visit to the clinic, with an average recognized duration of the infection of 4 weeks.

Culture

Hairs fluorescing under Wood's light or from areas of alopecia in which the majority of the hairs were broken off at the surface of the scalp, were epilated and cultured on Sabouraud's glucose agar containing 30 units of penicillin and streptomycin each per ml. and on Litman's agar. These were incubated at room temperature and identification on the fungus was based on cultural and microscopic characteristics.

Therapy

Each patient was carefully instructed in the method of therapy as follows: (1) shave scalp, (2) wash head with soap and water each night, (3) apply Di-Paralene to all scalp area with five to ten minutes massage in the morning and before bedtime (after shampoo), (4) wear a clean, white stocking cap at all times, (5) boil cap daily. Needless to say, some of the patients did not carry out these

TABLE I

Evaluation of 2% Di-Paralene in the treatment of tinea capitis

CLINICAL AND LABORATORY FINDINGS:	INFECTING FUNGUS:			
	M. audouini	*M. canis*	*T. rubrum*	*T. schoenleini*
I. Pre-Treatment				
Number of cases	12	1	1	1
Average age	6½ years	4	4	6
Sex	9 male, 3 female	1 male	1 female	1 male
Average duration of disease	5 weeks	3 weeks	4 weeks	1 week
Number with prior treatment without improvement	0/12	0/1	0/1	0/1
Number with positive fluorescence	6/12	1/1	0/1	0/1
Number with local scalp reaction*	4/12 (moderate)	0/1	1/1 (moderate)	1/1 (moderate)
Number with alopecia	12/12	1/1	1/1	1/1
II. Post Treatment				
Number with positive fluorescence	5/12	1/1	0/1	0/1
Number with local reaction	2/12	0/1	1/1	0/1
Number with alopecia cleared or greatly improved	4/12	0/1	0/1	0/1
Number cultures negative at 8 weeks	3/12	0/1	0/1	0/1
Number cured in under 8 weeks	2/12	0/1	0/1	0/1

* Patients with marked local reaction were excluded from the study.

instructions in a satisfactory manner, and some patients were dropped from the study because of continued lack of cooperation. At the time of visits to the clinic during the course of therapy, interim cultures were obtained. The therapeutic regimen was continued for a period of eight weeks, and all patients showing evidence of clinical inprovement were checked at 2 week intervals for six to eight weeks after therapy had been discontinued. The cases reported as cures met the following criteria: (1) no clinical evidence of infection. (2) no fluorescence under Wood's light after all treatment had been stopped and (3) repeated negative cultures from areas known to have been infected.

RESULTS

An initial trial of 2 percent Di-Paralene ointment on 15 patients with tinea capitis as determined by clinical picture and cultures, revealed sustained clinical improvement in only two (Table I).

However, several other patients had an encouraging initial response to this therapy but subsequently relapsed. In view of this observation, it seemed desirable to evaluate the effect of a higher concentration of the drug. Accordingly, 14 patients were treated with a 5 per cent Di-Paralene preparation in the manner previously outlined. The findings in this group are shown in Table II.

TABLE II

Evaluation of 5% Di-Paralene in the treatment of tinea capitis

CLINICAL AND LABORATORY FINDINGS:	INFECTING FUNGUS:		
	M. audouini	*M. canis*	*T. rubrum*
I. Pre-Treatment			
Number of cases	6	5	3
Average age	6 years	4½ years	5 years
Sex	All male	3 male, 2 female	All male
Average duration of disease	3 weeks	5 weeks	4 weeks
Number with prior treatment without improvement	6/6	4/5	1/3
Number with positive fluorescence	4/6	5/5	0/3
Number with local scalp reaction*	3/6 (moderate)	4/5 (moderate)	2/3 (moderate)
Number with alopecia	6/6	5/5	3/3
II. Post Treatment			
Number with positive fluorescence	3/6	2/5	0/3
Number with local reaction	0/6	0/5	0/3
Number with alopecia cleared or greatly improved	2/6	4/5	2/3
Number cultures negative at 8 weeks	4/6	4/5	3/3
Number cured in under 8 weeks	3/6	1/5	2/3

* Patients with marked local reaction were excluded from the study.

Of six patients infected with *Microsporum audouini*, three were clinically and culturally cured in less than eight weeks. One other patient had a consistently negative culture post-treatment, but alopecia due to the breaking off at the scalp of infected hairs persisted beyond the fourteenth week. In the group of five patients with *Microsporum canis* infection, only one could be considered cured both clinically and culturally within the eight week treatment period. Three of the remaining patients had negative cultures at eight weeks and beginning regrowth of hair in areas of the tinea capitis alopecia. However, between the 8th and 14th week, the cultures became positive and clinical signs of tinea capitis reappeared. Three children with *Trichophyton rubrum* infections were studied. All of these patients showed an initially favorable response to 5 per cent Di-Paralene ointment and were culturally negative at the end of the treatment period. However, one had persistent alopecia and subsequently developed a positive culture.

COMMENT

It would appear that the response to the 5 per cent Di-Paralene preparation was superior to that obtained with the 2 percent preparation, although in view of the limited number of patients in each of the groups studied it was felt that no cure rate could be established. Di-Paralene (5 per cent) has a higher cure rate than Miller and associates (41) have reported for undecylenic acid, sodium propionate or dinitrocyclohexyl but is not as effective as salicylanilide (3, 5).

SUMMARY

An antihistaminic preparation Di-Paralene (chlorocyclizene hydrochloride) is known to have *in vitro* fungistatic activity. This material in an ointment base has been evaluated in 29 children with tinea capitis.

1. Of fifteen children who were treated with two per cent Di-Paralene ointment only two could be classified culturally and clinically as cured.

2. Of fourteen children treated with a 5 per cent Di-Paralene ointment eleven showed an initially favorable response but only six were classified as cured.

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