

The Effect of 'Etisul' on the Fragmentation of *M. Leprae* in Lepromatous Leprosy

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Whilst there has not been complete agreement concerning the usefulness of Etisul as an anti-leprosy drug (for review of the literature see N. A. Torsuyev, 1962), T. F. Davey (1959 and 1960) and other workers have found that it is effective, and that Etisul acts mainly on the bacilli of normal morphology, causing them to become fragmented. Therefore it was decided to conduct a small-scale controlled trial with the prime object of determining the effect of Etisul upon the degree of fragmentation of the *M. leprae*.

Method

Eleven male patients were selected, all having been admitted to the institution between three and five months before the trial began. They were all highly positive lepromatous patients, having bacillary indices (B.I.) of at least 4. The B.I. was determined by the examination of five skin smears, expressed in terms of the particular scale in use in this institution at the time of the trial. Except for two patients (A3 and B3) none had received any anti-leprosy treatment prior to admission. All patients received general medical examination and were free from abnormality apart from their leprosy.

All the patients received DDS, beginning with small doses and increasing to a maximum of 400 mg./week at the beginning of the trial. Because it was hoped to show the effect of Etisul on the fragmentation of the bacilli patients were selected who had no history of lepra reaction, as this might have recurred and obscured the results. No serious lepra reaction occurred in any of the patients during the trial.

The patients were divided into two groups, Group A containing six patients, and Group B containing five patients. Group A received Etisul in addition to DDS, Group B formed the control, receiving DDS only.

The trial ran for a period of four months (17 weeks). Each patient received by inunction

5 ml. of Etisul three times a week (on Monday, Wednesday and Friday). The drug was applied to the back, the patients forming a circle and each man rubbing the back of the man in front. The inunction lasted for 20 minutes and the patients were allowed to take a bath one hour after the inunction ceased.

At the beginning of the trial smears of each patient were made in five sites and the B.I. determined, and at the same time the degree of fragmentation was recorded; this was expressed as the percentage of fragmented bacilli (including beaded forms) present in the slides, the percentage being estimated to the nearest 5% on the basis of a count of the bacilli.

At the end of the trial the smears were taken again and the B.I. determined, and again the percentage fragmentation was recorded. All the bacteriological examinations were done by the same technician, who did not know which patients were receiving Etisul and which were in the control group.

Toxic Effects

One patient (A5), who had a B.I. of 4.4 at the beginning of the trial, after three weeks treatment with Etisul, developed an urticarial eruption, beginning on the area of the back over which Etisul was being applied and spreading to involve the whole body within 24 hours. Etisul was discontinued. Little improvement followed the administration of antihistamines, both topically and systemically, but improvement was rapid when prednisolone was given orally; the steroid was withdrawn when the eruption had subsided and the patient has remained well since, continuing to take DDS.

No other toxic effects were reported.

RESULTS

The results are shown in the tables below. Improvement was expressed as a decrease in the B.I., and as an increase in the percentage of fragmented bacilli.

Group A – Etisul

Patient No.	At beginning:		B.I.	At end:		Improvement:	
	B.I.	% frag. ⁿ		% frag. ⁿ	B.I.	% frag. ⁿ	
A1	5.0	75	4.4	90	0.6	15	
A2	4.2	90	3.8	95	0.4	5	
A3 ¹	5.0	90	4.8	90	0.2	0	
A4	5.0	80	4.6	90	0.4	10	
A6	4.4	90	4.2	90	0.2	0	
Average	4.7	85	4.4	91	0.36	6	

Group B – control

Patient No.	At beginning:		B.I.	At end:		Improvement:	
	B.I.	% frag. ⁿ		% frag. ⁿ	B.I.	% frag. ⁿ	
B1	5.4	70	4.2	80	1.2	10	
B2	4.8	75	4.8	80	0	5	
B3 ¹	4.6	75	4.6	80	0	5	
B4	4.0	90	3.0	90	1.0	0	
B5	5.6	80	5.2	90	0.4	10	
Average	4.9	78	4.4	85	0.52	6	

(¹ – had received previous treatment)

LIMITATIONS OF THE METHOD

There are two main limitations in this trial, the first being the small number of patients involved; this was due to the desire to include as far as possible only patients just beginning Sulphone therapy, and to exclude those patients known to be liable to lepra reactions.

Secondly the estimation of the percentage fragmentation was a visual estimation and relatively inaccurate.

CONCLUSION

Within the limitations of this trial, no advantage has been shown to follow the use of Etisul in lepromatous leprosy, when the patients are receiving DDS, improvement being judged by the decrease in the Bacillary Index and the increase in the percentage of fragmented bacilli in the patients' smears. In addition there seems to be a real risk of toxic effects with Etisul treatment.

The B.I. and the percentage fragmentation will be determined and again compared after an interval, in order to determine any late effects. It will be recalled that the trial of Etisul lasted four months.

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