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Bacteriological Effect of Lamprene (Clofazimine) in Lepromatous Leprosy*

(Report of one year's treatment of 44 patients with 100 mg of Lamprene daily)

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The treatment of 44 lepromatous patients with 100 mg of clofazimine (Lamprene, Geigy) daily resulted in a rapid increase in the percentage of granular bacilli during the first 3 months of treatment, reaching 94% after 6 months of treatment. The bacterial index decreased in 1 year from 5.4 to 4.5. Three patients responded rather slowly. In only 1 patient was there no bacteriological improvement after 1 year of treatment. It is concluded that clofazimine (Lamprene) is an effective, rapidly-acting drug in lepromatous leprosy, and that the bacteriological effect is comparable with that of sulphones.

Introduction

The bacteriological effect of giving 100 mg of clofazimine (Lamprene) daily to patients with lepromatous leprosy has been investigated by a group of workers in different centres. All patients were classified on clinical and bacteriological grounds as lepromatous; patients with borderline features were excluded. This

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TABLE 1

Bacteriological progress in 44 lepromatous patients treated with 100 mg of Lamprene daily, showing Bacterial Index (BI) and percentage of bacilli intact (I), fragmented (F) and granular (G)

A. *Reactive patients* (18)

Biopsy / Patient	Onset				3 months				6 months				9 months				12 months			
		Percentage				Percentage				Percentage				Percentage				Percentage		
	BI	I	F	G	BI	I	F	G	BI	I	F	G	BI	I	F	G	BI	I	F	G
793	4	4	34	62	3	0	3	97	2	0	0	100	4	0	7	93	3	0	4	96
1417	4	3	40	57	3	0	2	98	3	0	0	100	3.5	0	5	95	4	0	6	94
1432	5.5	2	24	74	3	0	1	99	4	0	0	100	5	0	3	97	4	0	3	97
1378	4	0	21	79	2	0	5	95	3	0	4	96	2	0	3	97	2	0	0	100
1392	4.5	2	47	51	4	0	0	100	3	0	5	95	3.5	0	1	99	4	0	1	99
1049	3.5	0	26	74	2	0	1	99	3	0	6	94	3	0	0	100	3	0	6	94
1331	6	9	85	6	5	0	6	94	4.5	0	1	99	4.5	0	3	97	5	0	6	94
2073	5.5	0	32	68	5.5	0	4	96	4	0	10	90	3	0	16	84	2	0	7	93
14/67	4.5	0	23	77	6	0	31	69	6	0	6	94	5.5	0	2	98	5.5	0	2	98
32/67	6	3	36	61	6	0	2	98	6	0	1	99	6	0	6	94	5.5	0	30	70
94/67	5	8	46	46	5	0	20	80	5	0	3	97	5	0	4	96	5	0	0	100
102/67	6	3	75	22	5	0	11	89	6	0	3	97	6	0	15	85	6	0	0	100
7/68	4.5	0	28	72	5	0	29	71	4	0	1	99	5	0	0	100	4	0	3	97
LT	4	0	38	62	4,5	0	19	81	5	0	4	96	4	0	1	99	2	0	1	99
Z	6	3	90	7	6	0	28	72	6	0	16	84	6	0	3	97	4.5	0	11	89
S	5.5	3	26	71	5	0	8	92	5	0	6	94	4.5	0	3	97	4	0	0	100
LS	6	1	45	54	6	0	35	65	6	0	15	85	6	0	9	91	6	0	3	97
R	6	0	64	36	5	0	32	68	4	0	0	100	4	0	2	98	3.5	0	3	97
Average	5.0	2	44	54	4.5	0	13	87	4.3	0	5	95	4.5	0	5	95	4.1	0	5	95

Table 1 continued

B. *Non-complicated patients* (26)

2252	6	0	41	59	4	0	11	89	6	0	5	95	4	0	16	84	4.5	0	8	92
2254	6	0	22	78	6	0	20	80	6	0	11	89	5	0	11	89	6	0	3	97
2255	5	0	41	59	4.5	0	7	93	4.5	0	2	98	4	0	4	96	4.5	0	11	89
2262	6	1	36	63	6	0	18	82	5	0	11	89	3	0	7	93	1	0	0	100
2263	6	0	26	74	6	0	21	79	6	0	7	93	4	0	8	92	5	0	1	99
2265	5	1	38	61	6	0	12	88	6	0	3	97	5	0	4	96	4	0	0	100
2269	6	1	22	77	5.5	0	23	77	5.5	0	13	87	5	0	30	70	3.5	0	4	96
2270	5.5	0	35	65	6	0	16	84	5.5	0	1	99	4	0	9	91	4	0	1	99
45/67	6	4	60	36	6	0	5	95	5	0	2	98	5.5	0	2	98	5	0	8	92
80/67	6	0	28	72	5.5	0	12	88	6	0	6	94	6	0	3	97	6	0	9	91
85/67	5.5	2	66	32	5.5	0	9	91	5	0	8	92	5	0	5	95	4.5	0	12	88
93/67	6	1	38	61	6	0	7	93	6	0	0	100	6	0	0	100	6	0	0	100
138/67	6	2	43	55	6	0	12	88	5	0	2	98	5.5	0	0	100	4	0	1	99
151/67	6	3	61	36	6	0	1	99	5	0	1	99	6	0	2	98	6	0	4	96
V	5	2	75	23	4.5	0	17	83	6	0	6	94	5	0	4	96	5	0	2	98
P	6	0	50	50	6	0	31	69	6	0	11	89	6	0	28	72	4.5	0	53	47
L	5	1	64	35	5	0	24	76	5	0	28	72	5	0	32	68	5	0	26	74
BR	6	0	40	60	6	0	21	79	6	0	2	98	6	0	3	97	6	0	3	97
FO	6	4	50	46	6	2	27	71	6	0	4	96	6	0	6	94	5	0	5	95
FN	6	1	44	55	6	2	61	37	6	0	40	60	5	0	18	82	5	0	10	90
BO	5	3	52	45	6	0	19	81	5	0	2	98	5	0	2	98	5	0	1	99
478	6	8	86	6	4	0	4	96	6	0	0	100	4	0	2	98	4	0	1	99
1234	6	0	44	56	6	1	82	17	6	0	9	91	6	0	2	98	6	0	1	99
2739	4	1	54	45	5	0	3	97	5	0	7	93	3	0	4	96	3	0	6	94
2755	5	1	71	28	6	0	39	61	6	0	2	98	5	0	1	99	6	0	0	100
951	6	0	72	28	4.5	0	36	64	6	0	1	99	6	0	1	99	5	0	0	100
Average	5.6	1.5	49	50	5.5	1	24	75	5.6	0	7	93	5.0	0	8	92	4.7	0	7	93
Total average	5.4	2	46	52	5.1	0.1	18	82	5.1	0	6	94	4.8	0	6	94	4.5	0	6	94

report deals with 44 patients who at the beginning of the trial had a minimum Bacterial Index (BI) of 4+ (Ridley-Cochrane scale) and at least 20% solid staining bacilli. The patients were treated for 12 months with 100 mg of clofazimine daily, and this treatment, with few exceptions, was continued during periods of reaction.

The patients are divided into 2 categories: Group A (18 patients) had shown repeated severe reactions in the year prior to the beginning of treatment with clofazimine, while Group B (26 patients) consisted of patients who were not suffering from any complications.

Assessment

The bacteriological evaluation was based on the examination of serial biopsies, taken at the beginning of the trial and thereafter at 3-monthly intervals. In each patient the biopsy specimens were taken from the same lesion. All biopsies were processed in one laboratory and were examined by the same investigator, who, at the time of examination, did not know the bacterial counts of previous biopsies.

With this method of assessment, it is considered justifiable to include in one trial patients from several centres. Such a course would, in our opinion, be impracticable if the assessment was based on the examination of smears, because of differences of technique in different centres. A double-blind trial was not considered appropriate or necessary, partly because of lack of suitable patients, but also because the deposit of clofazimine in the infiltrates is easily recognizable in sections.

Results

The bacteriological effect of clofazimine on the groups of patients is shown in Figs 1 and 2. The effect on the individual patients is shown in Table 1.

Figure 1 shows that there is little difference between the 2 groups in the rates of increase in the percentage of granular bacilli and in the decrease of the bacteriological index. In both groups a rapid increase in the percentage of granular bacilli is seen in the first 3 months of treatment. The rate decreases in the second 3 months, while after 6 months, about 95% of the bacilli have already become granular. Further increase in this percentage is very slow.

The table shows that this result is applicable to the majority of patients. Out of 44 patients, only 4 showed a slower response to treatment (Group B: 2269, P.L.F.). Only 1 patient (P) did not show improvement after 1 year of treatment with clofazimine. This patient had advanced diffuse lepromatous leprosy. Failure cannot be ascribed to lack of intake or absorption of the drug, since the skin became markedly pigmented.

Occasionally fluctuations in the percentage of granular bacilli have been seen in this and in similar trials. These sections were re-examined in order to exclude possible errors in counting, but it was found that the counts were generally correct. It was not possible in most cases to establish whether the temporary increase in the percentage of fragmented bacilli was to be ascribed to a temporary increase of viable bacilli or to the fact that the biopsies were taken from a different part of the same lesion. Because the increase in fragmented bacilli was not accompanied by an increase in completely intact bacilli, the second possibility is the more likely.

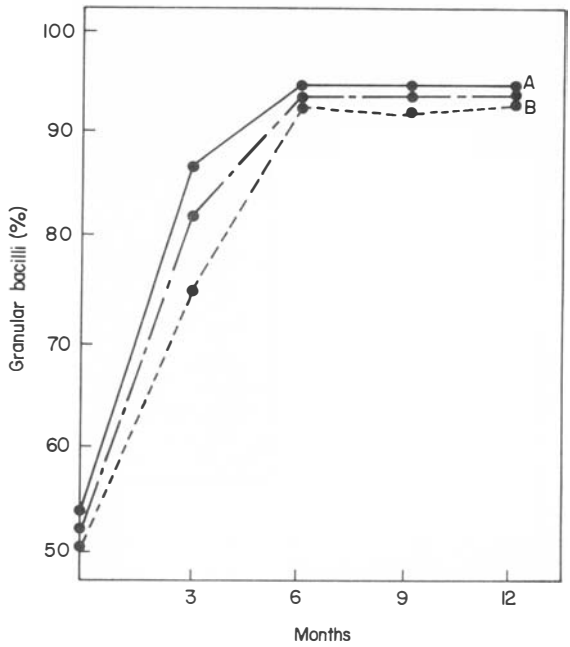

Fig. 1. Percentage of granular bacilli in 44 lepromatous patients treated with 100 mg of Lamprene (clofazimine) daily. – – – – Reactive patients A. ———— Uncomplicated B. – – – – – – All patients.

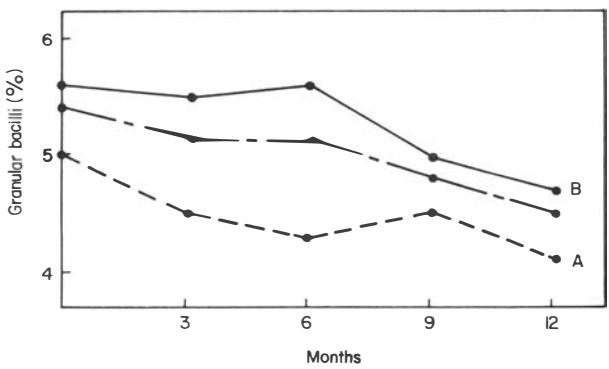

Fig. 2. Bacterial Index in 44 lepromatous patients treated with 100 mg of Lamprene (clofazimine) daily. – – – – Reactive patients A. ———— Uncomplicated B. – – – – – – All patients.

The decrease in the bacteriological index (Fig. 2) seems to be relatively slow. It should be kept in mind, however, that a high proportion of the patients started the trial with a BI of 6+ (indicating 1000 or more bacilli per microscopic field). Only after the number of bacilli has decreased below 1000 per field is a decrease in BI evident in this notation. The fall in the BI from 5.4 to 4.5 after 1 year of treatment is about the same as that found in patients treated with sulphones.

It is concluded that clofazimine (Lamprene) is a rapidly acting drug in leprosy and that the bacteriological effect of treatment is comparable with that of the sulphones.