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The Effect of Long-term Steroid Therapy on Patients Treated with Clofazimine (Lamprene)

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A study was undertaken in 18 leprosy patients and 31 controls to find out if Lamprene can prevent a flare-up of the infection with *Myco. leprae* during long-term steroid therapy. All patients were either BL or LL; some were given daily Lamprene 100 mg and prednisone 10 mg because of persistent reactions, others twice weekly Lamprene 100 mg and daily prednisone 10 mg for the same reason. The duration of treatment varied from 6 to 23 months. The control patients were given Lamprene only, either daily 100 mg or twice weekly 100 mg. Their reactions were less severe and therefore they did not require prednisone. It was found that in both groups (Lamprene plus prednisone and Lamprene only) there was a satisfactory reduction of the MI (Morphological Index) to zero or less than 1%. But as regards the BI (Bacteriological Index) the patients on Lamprene plus prednisone did clearly better than the patients on Lamprene only. It thus appears that long-term steroid therapy has no adverse effect on the BI and MI of lepromatous patients, provided that they are treated with Lamprene at the same time.

Introduction

It is a well known fact that during long-term steroid therapy an undiagnosed and therefore untreated infection with *Myco. tuberculosis* may flare up. With this in mind a study was undertaken in 18 leprosy patients on long-term steroid therapy to find out if Lamprene does prevent a flare-up of the infection with *Myco. leprae*.

Materials and Methods

The patients were divided in 4 groups:

(1) Patients on daily Lamprene and steroids	12
(2) Patients on bi-weekly Lamprene and steroids	6
(3) Patients on daily Lamprene	8
(4) Patients on bi-weekly Lamprene	33

The total number of patients studied was 49, all of them LL or BL. Some patients first belonged to one of the 4 groups and later to another.

Group 4: Lamprene twice weekly 100 mg

(a) Thirty patients suffering from reaction (ENL and fever), 8 of whom were found to be suffering from tuberculosis as well.
(b) Three patients with resistance against DDS.

If in spite of bi-weekly Lamprene reactions continued to occur, Lamprene was increased to 100 mg daily.

Group 3: Lamprene daily 100 mg

(a) Seven patients suffering from reaction, 5 of them with concomitant tuberculosis.
(b) One patient with resistance against DDS.

As Lamprene is an expensive drug and not always freely obtainable in India, it was sometimes impossible to increase the dosage to 100 mg daily to suppress reactions. In that case steroids (prednisone) were given according to a standard routine, starting with 40 mg daily and tapering off in 4 weeks to 10 mg daily.

Group 2: Lamprene twice weekly 100 mg and prednisone (40 to 10 mg) daily

(a) Four patients with chronic neuritis.
(b) Two patients with chronic reaction, one of them suffering from tuberculosis as well.

If in spite of bi-weekly Lamprene reactions continued to occur, Lamprene was increased to 100 mg daily.

Group 1: Lamprene 100 mg daily and prednisone (40 to) 10 mg daily

(a) Seven patients with chronic reaction.
(b) Five patients with chronic neuritis.
Seven patients in this group with extremely severe reaction and/or neuritis suffered from tuberculosis as well.

As far as possible bacteriological smears were examined every 3 months and only patients with at least 6 months treatment of the same type and with at least 3 smears were included in the various groups.

Results

In all patients there was a satisfactory reduction of the MI to less than 1% and in most cases to zero.

The average decline of the BI was as follows:

Group 1: Daily Lamprene and prednisone: 47% per annum, varying from 12 to 84%.
Group 2: Bi-weekly Lamprene and prednisone: 54% per annum, in 1 patient the BI increased by 14%, in the others there was a decline of up to 100%.
Group 3: Daily Lamprene: 25% per annum, in 2 patients the BI increased by 8 and 10% respectively, in the others there was a decline of up to 100%.
Group 4: Bi-weekly Lamprene: 37% per annum, in one patient the BI increased by 5%, in the others there was a decline of up to 100%.

TABLE 1

Group 1: Daily Lamprene and prednisone

	Period in months	First smear BI-MI	Last smear BI-MI	Decline BI per annum
1. M., BL, 1958, chronic neuritis	18	3.3–0.0	1.6–0.0	34%
2. G., BL, 1959, chronic neuritis	8	3.0–0.0	1.5–0.0	75%
3. D., LL, 1963, chronic reaction	10	4.5–0.0	3.5–0.0	27%
4. Y., LL, 1963, chronic reaction, tb	6	4.5–0.3	2.6–0.0	84%
5. K., BL, 1962, chronic neuritis, tb	8	3.1–0.0	2.1–0.0	48%
6. D., LL, 1954, chronic reaction, tb	19	3.5–0.0	1.1–0.0	43%
7. T., LL, 1941, chronic reaction, tb	13	3.1–0.0	1.8–0.0	39%
8. N., BL, 1954, chronic neuritis, tb	6	5.0–0.3	4.3–0.1	28%
9. S., BL, 1954, chronic neuritis	16	2.8–0.0	0.3–0.0	67%
10. L., LL, 1937, chronic reaction	9	2.6–0.0	1.5–0.0	56%
11. S., LL, 1956, chronic reaction, tb	21	3.5–0.0	0.5–0.0	49%
12. P., LL, 1928, chronic reaction, tb	23	4.6–0.3	3.5–0.0	12%
				562
				Average: 47%

TABLE 2

Group 2: Bi-weekly Lamprene and prednisone

	Period in months	First smear BI-MI	Last smear BI-MI	Decline BI per annum
1. D., LL, 1961, chronic reaction, tb	6	3.5–0.0	3.0–0.1	29%
2. A., BL, 1954, chronic neuritis	6	3.6–0.0	1.8–0.0	100%
3. I., BL, 1953, chronic neuritis	8	2.1–0.0	2.3–0.2	−14%
4. L., LL, 1937, chronic reaction	7	5.5–0.6	3.8–0.0	53%
5. G., BL, 1957, chronic neuritis	6	3.8–1.2	2.0–0.0	95%
6. S., BL, 1954, chronic neuritis	9	4.1–0.3	2.3–0.0	59%
				322
				Average: 54%

TABLE 3

Group 3: Daily Lamprene

	Period in months	First smear BI-MI	Last smear BI-MI	Decline BI per annum
1. M., LL, 1947, chronic reaction, tb	7	4.8–1.0	4.3–0.0	18%
2. J., LL, 1945, DDS resistant	6	5.0–2.3	4.6–0.3	16%
3. B., LL, 1959, chronic reaction	8	3.1–0.2	2.6–0.0	24%
4. R., LL, 1954, chronic reaction	7	4.3–0.5	4.5–0.2	−8%
5. V., LL, 1961, chronic reaction, tb	7	4.5–0.2	3.6–0.3	34%
6. D. LL., 1961, chronic reaction, tb	9	4.1–0.1	0.3–0.0	124%
7. N., BL, 1954, chronic reaction, tb	9	5.2–3.0	5.1–0.3	3%
8. T., LL, 1941, chronic reaction, tb	10	3.5–0.7	3.8–0.0	−10%
				201
				Average: 25%

TABLE 4

Group 4: Bi-weekly Lamprene

	Period in months	First smear BI-MI	Last smear BI-MI	Decline BI per annum
1. R., LL, 1959, chronic reaction	11	2.5–0.3	0.3–0.0	96%
2. K., LL, 1944, chronic reaction	12	4.1–0.6	4.1–0.2	0%
3. M., BL, 1947, chronic reaction	9	1.5–0.0	0.0–0.0	133%
4. R., LL, 1942, chronic reaction, tb	19	4.8–0.0	2.0–0.0	37%
5. B., LL, 1934, chronic reaction	7	4.1–0.6	3.5–0.3	25%
6. A., LL, 1937, chronic reaction, tb	22	3.0–0.0	0.0–0.0	55%
7. S., LL, 1050, chreoic reaction	28	4.5–0.2	0.8–0.0	35%
8. S., LL, 1949, chronic reaction	23	4.8–0.1	1.6–0.0	35%
9. J., LL, 1946, chronic reaction	9	5.0–0.1	2.6–0.0	64%
10. M., LL, 1945, chronic reaction	36	4.5–8.0	0.6–0.0	29%
11. B., LL, 1935, chronic reaction	25	5.0–1.0	4.8–0.5	2%
12. C., LL, 1935, chronic reaction, tb	7	3.8–0.0	2.3–0.0	68%
13. R., BL, 1951, chronic reaction	17	5.0–0.0	3.8–0.2	17%
14. Y., LL, 1937, DDS resistant	22	4.6–0.0	3.8–0.1	9%
15. S., LL, 1930, chronic reaction	18	4.6–0.0	2.1–0.0	36%
16. P., LL, 1952, chronic reaction	18	3.5–0.0	3.0–0.0	10%
17. H., LL, 1943, chronic reaction	27	5.3–4.0	1.0–0.0	36%
18. S., LL, 1947, chronic reaction	11	4.3–0.6	2.1–0.0	56%
19. V., LL, 1935, DDS resistant	6	4.6–1.5	4.3–0.0	13%
20. S., BL, 1940, chronic reaction	7	5.0–0.3	4.1–0.1	31%
21. Y., LL, 1955, chronic reaction	6	5.0–0.5	2.8–0.0	88%
22. S., LL, 1933, chronic reaction	7	4.0–0.0	3.6–0.0	17%
23. S., LL, 1943, chronic reaction	15	5.5–0.6	3.3–0.0	32%
24. M., LL, 1918, DDS resistant	9	4.0–1.1	3.6–0.0	13%
25. S., LL, 1950, chronic reaction	15	5.0–0.0	2.6–0.0	38%
26. S., LL, 1954, chronic reaction, tb	9	5.1–4.0	5.3–1.6	−5%
27. Y., LL, 1950, chronic reaction, tb	7	3.1–0.0	2.0–0.0	61%
28. A., BL, 1954, chronic reaction	15	5.0–0.0	2.3–0.0	43%
29. G., LL, 1939, chronic reaction	10	5.1–0.3	3.5–0.2	38%
30. P., LL, 1930, chronic reaction	16	5.1–1.5	3.3–0.0	26%
31. S., LL, 1947, chronic reaction, tb	28	2.1–0.0	0.0–0.0	43%
32. Y., LL, 1963, chronic reaction, tb	10	5.1–6.0	3.6–0.0	35%
33. D., LL, 1961, chronic reaction, tb	8	5.4–6.0	5.0–0.2	11%
				1227
				Average: 37%

Summary

	Average decline BI
Group 1: Daily Lamprene and prednisone	47% (tb patients 43%).
Group 2: Bi-weekly Lamprene and prednisone	54% (tb patients 29%).
Group 3: Daily Lamprene	25% (tb patients 34%).
Group 4: Bi-weekly Lamprene	37% (tb patients 38%).

Discussion

In both groups, with and without prednisone, a few patients showed a slight increase in BI. It is interesting to note that group 1 (daily Lamprene and

prednisone) seemed to do better than group 3 (daily Lamprene only) and that group 2 (bi-weekly Lamprene and prednisone) seemed to do better than group 4 (bi-weekly Lamprene only).

As the average decline of the BI in the patients with tuberculosis was about the same as the average decline of BI in the whole group, it does not seem likely that treatment of tuberculosis with streptomycin, INH and thiosemicarbazone had much influence on the reduction of the BI in these patients.