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Combined chemotherapy of multibacillary leprosy of 6 months' duration

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Introduction

It has been shown previously[1] that a regimen composed of rifampicin (RMP) 600 mg twice a week together with daily prothionamide (PRO) 500 mg and dapsone (DDS) 100 mg given during 6 months followed by 6 months of daily 100 mg DDS was effective in the treatment of multibacillary leprosy.

Since dapsone (DDS) is essentially bacteriostatic and slowly bactericidal for *Mycobacterium leprae*, the role of the dapsone monotherapy during the second semester in the above regimen may be questioned. It was therefore justifiable to explore the value of a 6 months' regimen.

Patients and procedures

Untreated multibacillary (MB) patients and relapsing, active MB patients were included in the study. Routine clinical and neurological examinations were performed; smears from one earlobe and two skin sites were examined for acid-fast bacilli. A skin biopsy was taken for histopathology. The following supervised treatment regimen was given: Regimen RPD—2 weeks RMP 600 mg 7/7, PRO 500 mg 7/7, DDS 100 mg 7/7, followed by 24 weeks RMP 600 mg 1/7, PRO 500 mg 7/7, DDS 100 mg 7/7.

Old MB cases treated for 5 years or more with DDS—and thus at risk of being infected with DDS-resistant organisms—were given instead clofazimine (CLO): regimen RPC.

The patients were seen regularly and formal clinical, neurological, bacteriological and histopathological examinations were performed at yearly intervals.

Results and Discussion

Between early 1982 and early 1984, 74 patients were taken into the trial, 54 males

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(73%) and 20 females (27%). The age distribution is presented in Table 1; 50% are 45 or more years old. Forty-seven patients had not been treated before; 27 were old cases clinically active having been treated for various lengths of time with DDS monotherapy, sometimes very irregularly; four of them had taken DDS for less than 5 years and thus received the regimen RPD. One new patient was erroneously treated with the combination RPC.

The mean bacterial index (BI) was 4·05. Many patients were lost because they were transferred to another centre where dapsone was continued because they still had a positive BI.

Because of the comparable antibacterial activity of DDS and CLO, the

Table 1. Age distribution of patients taken into the trial.

0–5	1
6–15	3
16–25	5
26–35	10
36–45	18
45+	37

Table 2. Follow-up of patients taken into the trial.

	NC		OC		Total
	RPD	RPC	RPD	RPC	
Total taken in	46	1	4	23	74
Died	2			2	4
Lost	18	1	3	13	35
Analysable	26	—	1	8	35
1Y	3			3	6
2Y	15		1	2	18
3Y	8			3	11

NC, new cases; OC, old cases; RED, rifampicin, ethionamide, dapsone; REC, rifampicin, ethionamide, clofazimine

patients who received RED and those who received REC may be considered together.

In total 29 patients (17 males (58%) and 12 females) were followed for 2–3 years, when the mean BI had dropped to 1·8. No relapses were observed. The hepatitis cases mentioned in a previous publication[2] occurred in patients who were not followed for two or more years. The observation continues.

The only criterion allowing the assessment of therapeutic regimens in MB leprosy is the eventual appearance of relapses.[3] It has been found[4] that 50% of relapses in MB leprosy occur within the first two years after the end of therapy. We can therefore conclude that the 6 months' regimen tested is not followed by relapses within the first two years after the end of therapy with a confidence limit of 11·9%.

Acknowledgments

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