

## Absence of Relapse within 4 Years Among 34 Multibacillary Patients with High BIs Treated for 2 Years with MDT<sup>1</sup>

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The World Health Organization (WHO) in 1982<sup>(10)</sup> recommended multidrug therapy (MDT) for multibacillary (MB) patients to be given for a minimum period of 2 years but, ideally, until skin smears became negative. The WHO Study Group meeting in 1993 reviewed these recommendations<sup>(11)</sup>. Since there was increasing evidence that 24 months of MDT was adequate for MB cases, the proviso to continue MDT until skin smears were negative was dropped. A study from Bamako, Mali,<sup>(8)</sup> reported only one relapse among 44 MB patients treated for 2 years with fixed duration therapy (FDT). Studies done by Becx-Bleumink<sup>(1)</sup> Ganapati, *et al.*<sup>(2)</sup> Katoch, *et al.*<sup>(6)</sup> Li, *et al.*<sup>(7)</sup> also show similar results. Due to operational constraints, many national programs are already adopting the 2-year MB regimen since it is much easier to implement. The group of 34 MB patients in the current study were a group of newly detected, previously untreated, MB patients who were given a fixed duration of MDT for 2 years.

### MATERIALS AND METHODS

Patients have been treated with MDT at SLR & TC, Karigiri, since 1981. The initial cohort of all MB patients available (1067) were given MDT, and they were all treated until smear negativity<sup>(4)</sup>. There were 35

patients in this group who had a bacterial index (BI) of 3+ or above. After this intake was completed (1 January 1984–31 December 1994), all new, previously untreated MB cases detected in our leprosy control program<sup>(5)</sup> have been put on FDT. A total of 261 patients have been included in this FDT trial. (These results will be presented in a subsequent paper).

For purposes of this study, the 34 patients with a BI of 3+ or more, with a minimum of 4 years of follow up after completion of 2 years of MDT, were investigated and the results are presented. The fall in BIs in this group is compared with the fall in BIs of the 35 MB patients with a BI of 3+ or more in the original cohort of 1067 treated until smear negativity, for whom 8–13 years of follow up after stopping conventional MDT was available.

### RESULTS

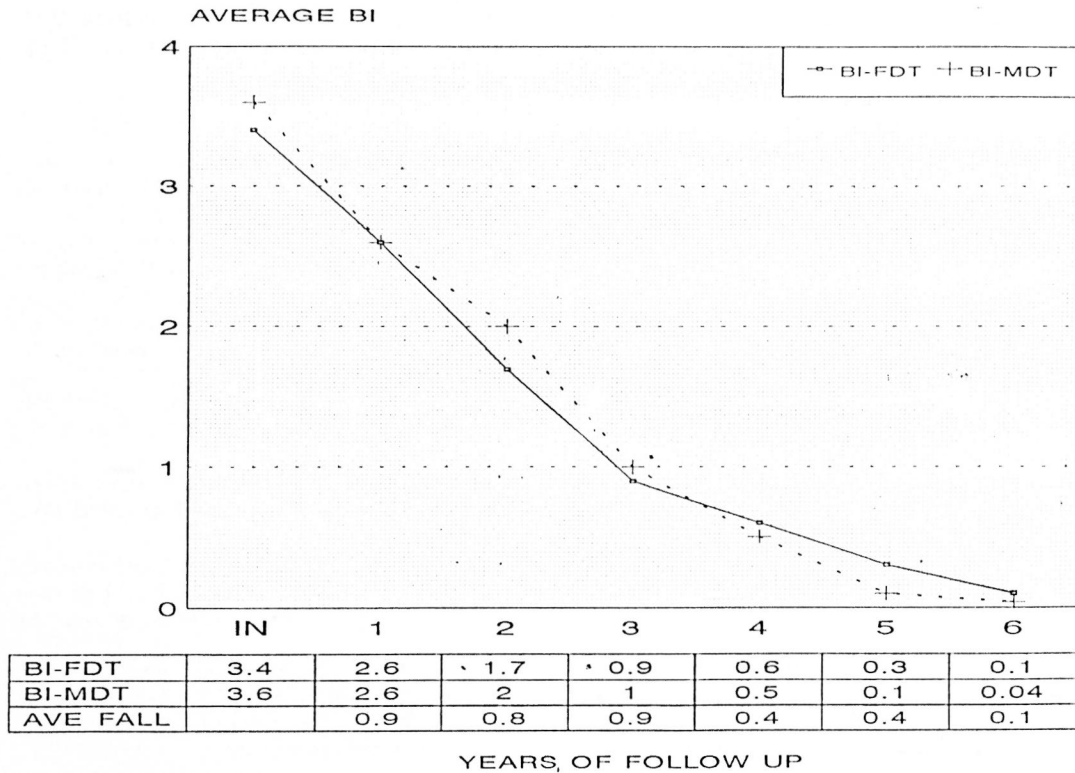
The average BI of the 34 MB patients was 3.4+ at the start of treatment (The Figure). This fell to 1.7 after 2 years of MDT, an average BI fall of 0.85 per year for the first 2 years of treatment. All of the patients were released from treatment after 2 years of FDT. During the subsequent 4 years of follow up, the BI continued to fall; after 4 years of follow up, the average BI was 0.1+.

The Table shows the number of cases and their BIs after the start of MDT. At release from treatment, after 2 years of MDT, two patients had already become negative. At the end of 4 years of follow up without any treatment, 25 out of the 34 (73%) patients had become negative.

The Figure shows the fall in BIs of the 34 MB patients treated with FDT compared with the 35 patients treated with MDT until skin smears became negative (conventional

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THE FIGURE. Fall in BI of patients on FDT or regular MDT with an initial BI of 3+ or more; a 6-year follow up.

MDT). The fall in BIs in both groups were similar. During the first 3 years, the average fall was 0.8–0.9 per year; in subsequent years, the rate of fall was smaller.

No relapses have been detected in either group. For those patients on conventional MDT, an average follow up of 10 years was available after release from treatment; for the 34 patients on FDT, a follow up of 4 years after the initial 2 years of FDT was available.

THE TABLE. Six-year follow up of 34 MB patients with a BI of 3+ or more.<sup>a</sup>

BI	Year					
	1	2	3	4	5	6
0	0	2	7	11	21	25
0.1–1.0	1	7	16	15	9	8
1.1–2.0	7	13	9	8	4	1
2.1–3.0	18	10	2	0	0	0
≥3.1	8	2	0	0	0	0

<sup>a</sup> Patients treated with 2 years of fixed duration MDT.

## DISCUSSION

The report of the Marchoux Chemotherapy Group<sup>(10)</sup> reported an overall relapse rate of 20% or 3.3 per 100 patient-years. The WHO report<sup>(11)</sup> gives the results of several studies on the chemotherapy of MB patients with MDT, either with conventional MDT (until skin-smear negativity) or for a fixed duration of 2 years. The risk of relapse was less than 1/1000 person-years, regardless of whether the patients were treated for 2 years or until smear negativity. However, fears have been expressed that the 2 years of FDT may be inadequate in patients with a high BI. The Marchoux study shows a high relapse rate, with an average incubation period of relapse of  $62.7 \pm 18.7$  months. This study shows that even in patients with a BI of 3+ or more, the fall in the BI was similar to patients who were treated until their skin smears became negative. Further, a follow up of 4 years after release from treatment showed no relapses. Thus, the results are better than that ob-

tained in the Marchoux study where two relapses were reported within 5 years of follow up. The current study showed no relapses up to the fifth year of follow up (October 1995) although results in this paper are for 4 years of follow up. This study requires further follow up to sustain its optimism.

### SUMMARY

Thirty-four multibacillary patients with a bacterial index (BI) of 3+ or more were treated with 2 years of WHO multidrug therapy (WHO/MDT). Treatment was then stopped and the patients followed for a minimum of 4 years. The rate of fall in the BI in this group without further treatment was similar to the rate of fall in the BI in an earlier group of similar patients treated with MDT until skin-smear negativity. No relapses have been seen.

### RESUMEN

Treinta y cuatro pacientes con lepra multibacilar (índice bacteriológico, BI, de 3+ o más) se trataron durante 2 años con la poliquimioterapia (PQT) de la OMS. Después de terminar el tratamiento los pacientes se siguieron durante un mínimo de 4 años. La tasa de caída en el BI en este grupo sin tratamiento posterior fue similar a la tasa de caída en el BI observada anteriormente en un grupo similar de pacientes tratados con PQT hasta que se tornaron BAAR negativos (linfa cutánea). A la fecha no se han observado recaídas.

### RÉSUMÉ

Trente-quatre patients multibacillaires avec un indice bactérien (IB) de 3+ ou davantage ont été traités par deux ans de polychimiothérapie de l'OMS. Le traitement fut alors arrêté et les patients suivis pour un minimum de 4 ans. La vitesse de diminution de l'IB dans ce groupe sans traitement ultérieur fut semblable à celle observée antérieurement dans un groupe semblable de patients traités par PCT jusqu'à négativation des frottis cutanés. Aucune récurrence n'a été observée.

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