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The Impact of Fixed Duration Multidrug Therapy on the Host and the Agent: A Pilot Study Using Clinical, Bacteriological, and Quality of Life Assessment Tools

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Sir,
World Health Organization (WHO) has introduced multidrug therapy (MDT) for leprosy since 1983 and later made it fixed duration treatment. Still later, the WHO has reduced the duration of multibacillary (MB) MDT regimen from 24 months to 12 months and eliminated the need for follow-up visit and slit-skin smear examination. Although fixed duration treatment has led to massive organizational success and resultant decrease in prevalence and annual case detection rate, follow-up data after completion of WHO MDT are largely lacking particularly from this part of the world. So, we, in a tertiary care center of eastern India, conducted a study among patients who have completed WHO MDT 6 months to 2 years earlier for assessment of clinical, microbiological, and quality of life (QoL). We evaluated the patients for clinical improvement, episodes of reaction, appearance of new lesions, status of slit-skin smear, and overall QoL using Bengali and Hindi versions of Dermatology Life Quality Index (DLQI) scale. We also performed DNA polymerase chain reaction (PCR) for Mycobacterium leprae from the patients' tissues to find PCR positivity in these patients.

A total of 77 patients of Hansen's disease who had completed WHO MDT treatment from 6 months to 2 years earlier at our center were contacted by means of either telephonic or postal communication. These patients were asked to follow-up for evaluation. Only 25 patients turned up with the response rate being 32.4%.

Among the study participants, 21 (84%) participants were male and 4 (16%) were female. Of the 25 patients, 23 had MB and 2 had paucibacillary (PB) leprosy. The age varied from 19 years to 51 years with the mean age being 37.04. Clinically, 22 (88%) patients had borderline leprosy, 2 (8%) had tuberculoid leprosy, and 1 (4%) had lepromatous leprosy. Of these patients, 23 (92%) patients received MB MDT and 2 (8%) PB MDT [Table 1].

Of 25 patients examined clinically, 11 patients showed complete healing, 7 patients had partial healing, and 7 presented with no sign of healing. Changes in the lesions were present in 14 patients in the form of redness, scaling, and pigmentation. Of the 7 patients who had no sign of healing, 5 presented with signs of activity and relapse in the form of appearance of new nerve involvement (2; 8%), appearance of new lesion (5; 20%), and the appearance of new deformity (1; 4%). Type 1 reaction was seen in 8 (32%) patients and Type 2 reaction in 3 (12%).
Correspondences

They found lower number (26.94%) of MB cases compared to 92% in our study.

Epidemiological data in our study correlated well with a similar study done by Vara et al. from India but differ considerably from a study done in Thailand by Dasananjali et al. They found lower number (26.94%) of MB cases compared to 92% in our study.

Clinically, evidence of relapse was presence of any of the followings, i.e., occurrence of new skin lesions, extension of previous lesions, and new nerve involvement. Of 25 (20%) patients showed clinical signs of relapse.

QoL assessment was done at presentation for all the patients. The mean score was 7. The highest score that was obtained was 18 and the least score was 0. Six patients had a score above 11 indicating very large effect on patients' life and 7 patients showed a score between 6 and 10, which indicated moderate effect. We have used Bengali, Hindi, and English versions of standard DLIQI questionnaire.

The poor turnover (32.4%) of the patients in our study could possibly be attributed to inaccurate entry of address or phone number, and/or low socioeconomic status and education level in this part of India. On the other hand, it might be that most of the patients had complete healing and they did not respond to follow-up call. This fact was reflected in the high positive and relapsed cases among the respondents.

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Of 25 patients, 6 were slit-skin smear positive. PCR by multiplex PCR was done on samples of all the patients, out of which, 23 (92%) were positive showing the presence of bacilli [Table 2].

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Clinically, evidence of relapse was presence of any of the followings, i.e., occurrence of new skin lesions, extension of previous lesions, and new nerve involvement. Of 25 (20%) patients showed clinical signs of relapse. This finding was similar to the finding of Vara et al. who found evidence of relapse in 26 out of 100 (26%) patients they followed up. However, in some other studies, where follow-up was done for a longer period of time, clinical evidence of relapse was found to be much lower (2/163; 1.2%). The higher rate of relapse in our study, which might have led to such a high number of relapses.

Type 1 reaction was seen in 8 (32%) patients and Type 2 reaction was seen in 3 (12%) patients. These results were similar to results obtained by Balagon et al. who found that 38/139 (27%) patients experienced one or more reversal reactions, while 7/139 (5%) had erythema nodosum leprosum (ENL) after completion of 1 year of therapy.

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MDT. They highlighted the fact that reactionary states and thereof the ensuing morbidity to patients were common even 1 year after completion of MDT, especially so in MB patients.

Microbiological evaluation was done in our study using the slit-skin smear and PCR to identify M. lepra DNA. Of 25 patients, 6 (24%) were slit-skin smear positive. A study done in northeastern Thailand by Dasananjali et al.\(^3\) showed that at the end of follow-up period of 10 years, they still had 32 positive slit-skin smears out of 188 patients (12.23%).

The PCR positivity for M. lepra was seen in 23 (92%) out of 25 patients. This high level of positive result could be because of the fact that the time elapsed between cessation of MDT and follow-up in our study was less, and it might not be enough for dead bacteria and its DNA to be cleared by body.

We had also performed QoL assessment of our patients using the DLQI which has been validated for leprosy. A good number (6; 24%) of the patients were found to be largely affected by leprosy even after completing MDT. Of these 6 patients, 2 had a relapse, while 5 had reaction episodes. It was evident that both relapse and reactions affected the patient’s life poorly. Furthermore, there were 7 patients (28%) who had their lives moderately affected.

We have made huge strides over the past decades in achieving leprosy elimination, and the vision is to achieve leprosy eradication. Although we have examined a very small number of patients due to limited time and resources, our study points towards a possible good number of reaction and relapses in the patients who have already completed MDT. It is also important to note that even after the completion of treatment and apparent cure of the disease; leprosy affects QoL of these patients.

The study was limited by low sample size, inability to do histopathology for confirmation of the disease due to limited ethical permission, and lack of longitudinal analysis. We understand the need to conduct a longitudinal study with larger cohort for more comprehensive analysis of the disease status after completion of WHO MDT.

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Conflicts of interest
There are no conflicts of interest.

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