# Clinical and histological activity after short duration multi drug therapy for leprosy

K K M B K Silva[1], C N Gunasekera[2], J Fernando[3]

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**Abstract**

The WHO recommended short duration multi drug treatment (MDT) regimens were adopted for treatment of leprosy in Sri Lanka since early 1990. Although the relapse rates after this short duration MDT is very low according to the data published by WHO, in clinical practice significant number of patients present with persistent or clinically active lesions and relapses. This study was carried out on leprosy patients who had been diagnosed and completed their recommended MDT for 6 months for paucibacillary (PB) leprosy and 12 months for multibacillary (MB) leprosy. Clinical and histopathological activity graded as active, resolving and inactive were studied in these patients by doing skin biopsies and thorough clinical examination. In the PB group (17 patients) at the end of the treatment, 3 (17%) showed clinically active disease, 1 (6%) showed resolving lesions and other 13 (76%) were clinically inactive. Histopathologically 5 (29%) showed active disease and 12 (71%) were inactive. In MB group (22 patients) 7 (33%) showed clinically active disease, 3 (14%) showed resolving lesions and 12 (54%) were clinically inactive. But histopathologically there were 9 (41%) patients with active lesions and other 13 (59%) were inactive histologically. The study emphasized that although the short duration MDT was aimed at increasing patients compliance and cost effectiveness, there may be incomplete resolution of the disease histologically more than clinically and this was more significantly seen in MB patients than the PB patients. It also showed that the clinical resolution did not correlate well with the histological activity in a significant number of patients. Considering these factors we recommend careful follow up of these patients with clinical and histological active disease, over a long period of time, with serial skin biopsies and microbiological evaluation and where necessary continue the treatment for an additional period of 6-12 months, specially in MB type.

## Introduction

In ancient times leprosy was regarded as contagious, mutilating and incurable disease. Dapsone was the first drug introduced as monotherapy in 1940s. But the resistant strains of *Mycobacterium leprae* developed against dapsone. In 1960s the addition of clofazamine to dapsone as combination chemotherapy helped to combat the resistant organisms[1]. Introduction of rifampicin, which is a potent bactericidal agent, to the treatment regimen improved the efficacy more.

In 1981 the WHO recommended multidrug treatment (MDT) regimens for treatment of leprosy. For MB leprosy, combination of rifampicin, clofazamine and dapsone was recommended for 24 months and for PB, combination of rifampicin and dapsone was recommended for 6 months. In 1996, with the aims of increasing compliance and the cost effectiveness, the WHO revised the treatment strategy which recommended even a shorter course of treatment for MB patients i.e. only 12 months treatment with the same drug combination.

In Sri Lanka since 1998 these short duration MDT regimens have been used in treatment of leprosy. Although the relapse rates after this short duration MDT regimens are very low, according to the data published by WHO[2] in clinical practice, significant number of patients present with persistent or clinically active lesions and relapses even after the completion of their treatment. In Sri Lanka no published data are available on the efficacy of MDT treatment and their clinical and histological characteristics after the treatment.

## Objectives

The study was undertaken to assess these leprosy patients clinically and histopathologically after starting MDT for the scheduled duration and to assess the correlation between these two parameters.

## Setting

Dermatology outpatients' clinic North Colombo Teaching Hospital, Ragama.

## Patients and method

The study was carried out on patients who were diagnosed clinically and histopathologically as having leprosy. There were 17 PB patients and 22 MB patients who completed their treatment from 1st January to 31st June 2003.

[1]*Registrar in Dermatology*, [2]*Consultant Dermatologist*, [3]*Consultant Pathologist, North Colombo Teaching Hospital, Ragama.*

**Table 1. Clinico-pahological correlation in PB and MB groups**

| Type of Leprosy | PB Group | | | MB Group | | |
|---|---|---|---|---|---|---|
| | Active | Resolving | Inactive | Active | Resolving | Inactive |
| Clinical assessment | 3<br>17% | 1<br>6% | 13<br>76% | 7<br>33% | 3<br>14% | 12<br>54% |
| Histopathological assessment | 5<br>29% | -<br>- | 12<br>71% | 9<br>41% | -<br>- | 13<br>59% |

Skin biopsies were done from most representative skin lesion under local anesthesia. The serial sections stained with haemotoxylin and eosin were assessed histopathologically and graded as active, resolving and inactive according to the type of granuloma, granuloma fraction[3], nerve inflammation and the percentage of lymphocytic of the dermis. The clinical activity was also graded after a thorough clinical examination to find the persistence of erythema and infiltration, whether new lesions appeared or whether there was an increase of anesthesia of the lesions.

All patients were followed up monthly during treatment. Skin biopsies and clinical features were recorded and compared at the onset of therapy and at the completion of therapy.

## Results

The study included 39 leprosy patients (17 PB and 22 MB). In the PB group at the end of the 6 months, treatment 3 (17%) showed clinically active disease, 1 (6%) showed resolving lesions and others 13 (76%) were clinically inactive. Histopathologically 5 (29%) showed active disease and 12 (71%) were inactive.

In MB group of the 22 patients 7 (33%) showed clinically active disease 3 (14%) showed resolving lesions and 12 (54%) were clinically inactive. Histologically there were 9 (41%) patients who showed active lesions and 13 (59%) were histologically inactive.

## Discussion

The study has emphasized that although short duration MDT was aimed at increase patients compliance and cost effectiveness, there may be incomplete resolution of the disease histologically more than the clinically suspected. This problem was more significant in MB group than in PB group (Table 1).

This study has also shown that the clinical resolution does not correlate well with histological activity in significant numbers, showing persistent of histological activity in spite of clinical resolution[4].

Therefore it is reasonable to expect that a certain percentage of these patients with active disease may present with relapses in future. We recommend careful follow-up of these patients over a long period of time with serial biopsies and microbiological evaluation whenever nessesary. If clinical histological or microbiological evidence indicates increase activity compared to baseline parameters, MB treatment is recommended for an additional period of 6-12 months.

## References

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