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**Original Article**

# Relapses in Multibacillary (MB) and Paucibacillary (PB) Leprosy after Treatment with Standard Multi-drug Therapy (MDT) : A Retrospective Analysis of Patients attending Leprosy Clinic of a Tertiary Care Hospital of Northern India

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Since the introduction of multi-drug therapy, multiple changes were made in the duration of therapy. But still there are wide variations in reported relapse rates. Most of these studies concentrated on smear positive multibacillary cases. Aim of this study was to study the frequency, time interval and possible risk factors for relapse in both multibacillary and paucibacillary leprosy cases in leprosy clinic at a tertiary care hospital. We analysed the records of patients registered between April 2014 and March 2019. The study included 132 MB patients and 12 PB patients who were treated with MBMDT and PBMDT respectively as per WHO guidelines. Among the cases analyzed, 7 out of 132 (5.30%) MB cases and 3 out of 12 (25%) PB cases relapsed [Total =6.94%]. The relapse rate with MDT- MB was lower than MDT - PB, but it was still higher as compared to other studies as mentioned earlier. Eighty percent of the relapse were observed within 5 years after RFT showing early occurrence of the relapse. Treatment and follow up modification is required for better management of both PB and MB leprosy cases at tertiary level centres. Combined chemo-immuno therapy in higher BI patients and 3-drug 6-month regimen for PB leprosy has shown good results. However, a longer follow up involving a larger sample size with PB and MB patients represented as per field conditions is needed to have a better idea about the long term efficacy of MDT regimens.

**Key words** : Leprosy, Paucibacillary, Multibacillary, Relapse, Multi drug therapy.

## Introduction

Leprosy is a disease that predominantly affects the skin and peripheral nerves, resulting in neuropathy and associated long-term consequences, including deformities and disabilities. The disease is associated with a lot of stigma, especially when deformities are present (WHO 2018).

In 1982, a World Health Organization (WHO) Study Group recommended the introduction and implementation of multidrug therapy (MDT) which was an important development in

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the history of leprosy control. All multibacillary (MB) patients were treated with MDT multibacillary regimen (MBR) till smear negativity or atleast for 24 months whichever was later (WHO 1982).

In 1994, standard 24 month regimen was recommended for all patients irrespective of the degree of bacteriological positivity [WHO 1993]. The recommended duration was reduced to 1 year in 1998, because relapse rates after MDT were widely reported to be low (WHO 1998). But still there are wide variations in reported relapse rates with WHO multidrug therapy in different regions. During 2016, 2743 cases of leprosy relapse were reported by 54 countries. Brazil reported 1431 cases, India 536 and Indonesia 229; the remaining 547 cases were reported by 51 countries (WHO 2017). Relapses can be due to treatment failure, inappropriate choice of regimen, and due to poor patient compliance. With the emergence of secondary drug resistance in treated or relapsed patient (Matsuoka 2010) and increasing number of cases with high initial bacillary load, there is an urgent need to review the current guidelines of "fixed duration therapy" (FDT) for leprosy.

In the present study, we evaluated the recent data to determine the frequency, time interval and possible risk factors for relapse in Multibacillary (MB) and Paucibacillary (PB) leprosy after 1 year and 6 month's treatment respectively with the standard multi-drug therapy (MDT).

**Materials and methods**

This was a retrospective record based analysis conducted in the Hansen's clinic of department of dermatology, venereology and leprosy at Government medical college, Amritsar. We reviewed the medical records of leprosy patients registered between April 2014 and March 2019 i.e. 5 years and excluded those of incomplete medical records. Clinical and demographic data of 144 patients was collected from the records and evaluated. The study included 132 MB patients and 12 PB patients who were treated with MBMDT and PBMDT respectively as per WHO guidelines (WHO 2012) Patients were classified clinically according to the Ridley-Jopling spectrum as tuberculoid (TT), borderline tuberculoid (BT), mid-borderline (BB), borderline lepromatous (BL) and lepromatous (LL) (Ridley & Jopling 1966). In addition some patients were also classified as indeterminate (I), histoid (H) or pure neuritic leprosy (PNL) wherever applicable (IAL 1982). Details of type and onset of time of reaction were noted and analysed. Deformities were classified according to standard WHO grading system (WHO 1988, Brandsma & van Brakel 2003).

In the present study, a case of relapse was defined clinically as the occurrence of fresh skin and nerve lesions, increase in the extent of lesions, infiltration and erythema, positive skin smears for AFB in previously negative cases; and in bacteriologically positive cases during surveillance, an increase in BI by two logs at any site over the previous BI in two successive examinations. Any sudden redness (showing activity in lesion), swelling of the lesion with or without new lesion especially in the first 6 to 12 months of follow up, was first considered as late reaction (Ramu 1995). All such patients were put on corticosteroids 40mg daily (up to maximum of 1mg/kg/day). If there was no obvious change in morphology of lesion (inflammation), or appearance of new lesion in 4 weeks on steroids, the patients were considered as to have relapsed (WHO 1998).

All the patients were treated according to WHO guidelines as used by Indian National Leprosy Eradication Programme (NLEP) i.e. paucibacillary (PB) patients received rifampicin and dapsone for 6 months, while multibacillary (MB) patients were treated with rifampicin, dapsone, and clofazimine for 12 months. After release from

treatment (RFT), in the initial 2 years of follow-up, all patients were reviewed every 3 months; later the patients were followed up every 6 months or less frequently at the leprosy clinic of our institute till the time of analysis. Subjects were also encouraged to report whenever they experienced symptoms suggestive of reactions/ nerve function impairment. Assessments included whole body clinical examinations and slit-skin smears which, to the greatest extent possible, were done annually or when new lesions were noted.

The data was filed and processed using Microsoft Excel software, 2007 version. The statistical analysis was performed using IBM SPSS Statistics version 24.0. Descriptive analysis was used for the baseline characteristics. Difference between the groups was analysed using chi square and t – test. A *p* value less than 0.05 was considered to be statistically significant.

**Results**

Among 144 patients reviewed, 12 (8.3 %) were paucibacillary (PB) and 132 (91.7 %) had multibacillary (MB) disease. (Fig. 1) The demographic and clinical characteristics of the patients are summarized in Table 1. Among the patients, there were 32 females (22.2 %) and 112 males (77.8 %) with a mean age at presentation being 36.78 ± 15.79. years for females and 36.59 ± 16.58 years for males. Among the relapse cases also, male predominance was seen with male : female ratio of 3 : 2 (n=10). 94 (65.3%) patients were local residents of Punjab, and 50 (34.7%) patients were migrants from other states mainly Uttar Pradesh, Bihar, Jharkhand, Orissa, Uttrakhand and Himachal Pradesh. The proportion of

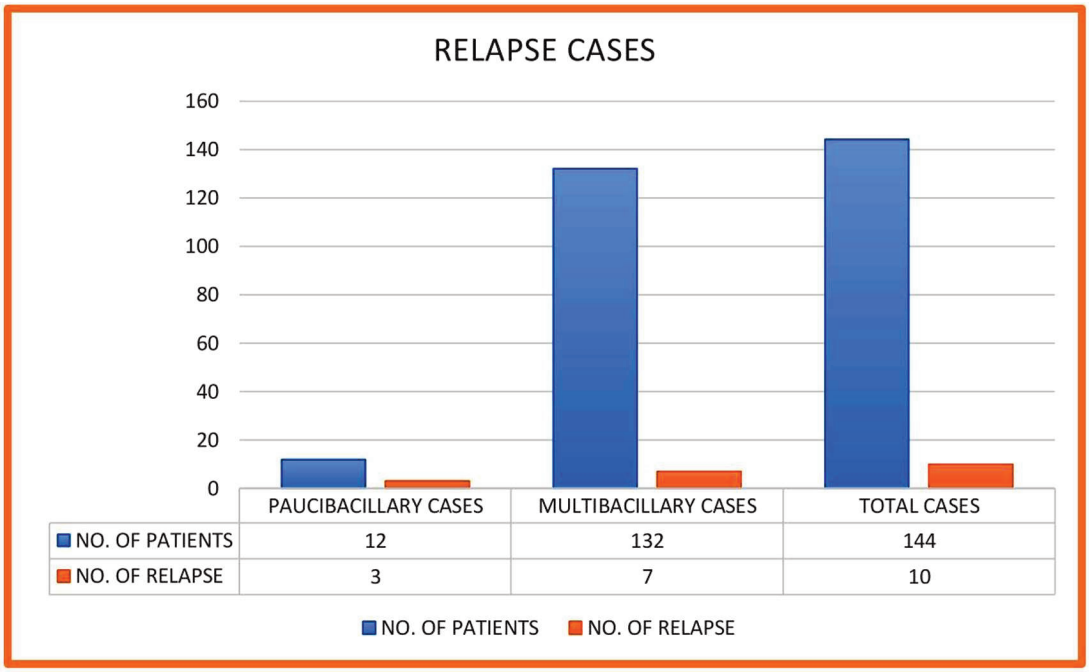


**Fig. 1 : No. of relapse among paucibacillary, multibacillary and total cases**

childhood leprosy (<15 years of age) was 5.55% (8; *n* = 144).

Among 144 cases (as shown in Table 1), 50 (34.72%) were classified as lepromatous leprosy (LL), 46 (31.94%) as borderline tuberculoid (BT), 16 (11.11%) as pure neuritic leprosy (PNL), 12 (8.33%) as mid borderline (BB), 9 (6.25%) as borderline lepromatous (BL), 8 (5.56%) as tuberculoid (TT), 2 (1.39%) as histoid (H) and 1 (0.69%) as indeterminate (I) leprosy.

**Table 1 : Demographic characteristics and background clinical status.**

| Age | Number Percentage<br>Mean age =36.63<br>(S.D. =16.35) | |
|---|---|---|
| **Gender** | | |
| Male | 112 | 77.8% |
| Female | 32 | 22.2% |
| **Residence** | | |
| Punjab | 94 | 65.3% |
| Other states | 50 | 34.7% |
| **Clinical forms of leprosy** | | |
| LL | 50 | 34.72% |
| BL | 9 | 6.25% |
| BB | 12 | 8.33% |
| BT | 46 | 31.94% |
| TT | 8 | 5.6% |
| I | 1 | 0.69% |
| H | 2 | 1.39% |
| PNL | 16 | 11.11% |
| **Treatment Regimen** | | |
| PB | 12 | 8.3% |
| MB | 132 | 91.6% |
| **Leprosy Reaction** | | |
| No | 111 | 77.08% |
| Yes | 33 | 22.92% |
| **Deformity** | | |
| No | 68 | 47.22% |
| Grade 1 | 26 | 18.06% |
| Grade 2 | 50 | 34.72% |
| Total Patients = 144 | | |

Thirty three (22.92%) patients presented with lepra reactions (Type 1 and Type 2) at the time of initial presentation to our clinic. Among them, 24 (72.73%) were males and 9 (27.27%) females. Thirty two of these patients belonged to multibacillary leprosy and only single patient belonged to paucibacillary group. (p value =0.21 ; not significant) . Among these patients, 10 showed signs and symptoms suggestive of type 1 lepra reaction and the rest 23 were suggestive of type 2 lepra reaction. During the course of treatment, 13 patients were relieved of the symptoms, 5 showed persisting symptoms, 4 were shifted or moved out and the remaining 11 patients were either irregular or lost to follow up. None of them presented with relapse during the mentioned study period. WHO Grade II deformity was present in 50 patients (34.72 %) and 26 (18.06 %) had Grade I deformity. Among all these, only one patient of PB group had grade 1 deformity. (p value = 0.005*).

Defaulting from treatment was observed in 19 out of 144 patients (13.2%), either by failing to take the drugs regularly (2 patients) or by not attending treatment centres / lost on follow up (17 patients). Those two patients who did not complete their MBMDT packs in 18 months were restarted with new course of MDT, And later on follow up no relapse was seen among these patients.

**Paucibacillary group**

Twelve out of 144 belonged to paucibacillary group. Among them 6 were diagnosed as borderline tuberculoid (BT), 5 tuberculoid (TT), and 1 as indeterminate leprosy. All patient

received PB-MDT. In this group, 3 (25%) relapse cases were found. All patients were smear negative at their initial examination. One patient of TT relapsed after 20 years after release from treatment (RFT), and other 2 patients of BT after 1.5 years and 4 years. All these patients presented with appearance of new lesions or extension of their previous lesions. All patients were smear negative at the time of relapse. 1 out of 3 relapse cases had no BCG scar (Table 2).

**Multibacillary Group**

In this group of 132 patients, there were 7 (5.30%) relapses, 5 were classified 'LL', 1 'BL' and 1 'BB' at their initial examination. Five patients were smear positive, (2+ - 6+) and 2 smear negative initially. Five patients relapsed within 2 years of RFT, one after 4 years and one after 15 years. Most of these patients presenting as clinical relapse, had the appearance of new patches and infiltrated plaques, diffuse infiltration becoming prominent (Fig. 2) and increase in the area of sensory loss. Their BI was higher or persistent when compared to the status of BI at RFT. One caseshowed reaction also. 2 out of 7 relapse cases had no BCG scar (Table 2).

**Fig. 2 : Relapse in a lepromatous leprosy case**

**Table 2 : Profile of relapse patients**

| S. No. | Type | AGE / SEX | Duration of MDT (months) | Initial BI | BI at relapse | Signs of reaction | Lesions* | Time of relapse (years) | BCG Vaccination |
|---|---|---|---|---|---|---|---|---|---|
| 1 | TT | 38/M | 6 | 0 | 0 | - | Yes | >5 | Yes |
| 2 | BT | 30/M | 6 | 0 | 0 | - | Yes | 2-5 | Yes |
| 3 | BT | 34/M | 6 | 0 | 0 | - | Yes | <2 | No |
| 4 | BB | 60/F | 12 | 0 | 1 | - | Yes | 2-5 | No |
| 5 | BL | 35/F | 12 | 0 | 0 | - | Yes | <2 | Yes |
| 6 | LL | 21/M | 12 | 6 | 6 | - | - | <2 | No |
| 7 | LL | 40/F | 12 | 6 | 6 | - | - | <2 | Yes |
| 8 | LL | 45/M | 12 | 6 | 4.4 | - | Yes | <2 | Yes |
| 9 | LL | 35/M | 12 | 5 | 4 | - | - | <2 | Yes |
| 10 | LL | 58/F | 12 | 2.5 | 3 | - | Yes | >5 | Yes |

**Discussion**

The world has now reached a status of leprosy elimination with the help of effective national leprosy control programmes and WHO MDT (WHO 2012). The appropriate duration of MDT for MB patients is the time required to reduce the size of viable bacterial population to such an extent that the rifampicin (RMP) resistant mutants are completely eliminated and the great majority of drug susceptible organisms are killed ( Ji 1985). As in the case of other infectious diseases, the relapse rate is a crucial parameter in assessing the long-term efficacy of chemotherapy. The relapse rate after WHO recommended MDT regimens is generally accepted to be low. A WHO questionnaire survey reported that the cumulative risk of relapse was 0.77% for multi-bacillary (MB) leprosy patients, 9 years after stopping MDT. (WHO 1995) Other follow-up studies have reported relapse rates varying from less than 1% to 20.0% (Chen et al 1999, Jamet & Ji 1992, Jamet & Ji 1995). The AMFES study reported no relapses after a mean duration of follow up of 5 years, (Gebre et al 2000) and a more recent paper reported no relapses after a follow-up of 13 years (Shaw et al 2003). In Agra field based study, overall relapse rate was observed as 1.97/100 persons years in the MB cohort treated with 12 months MDT (Kumar et al 2013).

Relapses could be due to drug resistance, treatment failure, re-infection or the growth of persister organisms. Persisters are organisms which are either non-metabolising or are lying dormant in inaccessible areas of the body so that they cannot be reached by the drugs during treatment. Once treatment is discontinued however, they may start multiplying again causing relapse, though they might stay undetected for sometime despite regular follow-up with slit skin smears until skin lesions appeared (Pattyn et al 1976, Sehgal et al 1996).

In the current study, 7 out of 132 (5.30%) MB cases and 3 out of 12 (25%) PB cases relapsed [Total =6.94%]. The relapse rate with MDT- MB was lower than MDT – PB, but it was still higher as compared to other studies as mentioned above. The World Health Organization (WHO) recommends MDT for a fixed duration of 6 months in paucibacillary (PB) leprosy patients regardless of the clearance of skin lesions or presence or absence of acid–fast bacilli in the skin (Fine 1982). Several patients also develop new lesions after completion of treatment which may be regarded as relapse or late reactions. This may also due to treatment inefficacy because of clinical mis categorization of MB leprosy with few lesions as PB cases. In the current study also, two patients of BT leprosy received 6 months PBMDT and relapsed after 1.5 and 4 years. Long term monitoring of activity of lesion in PB leprosy should be done even after RFT. We can consider the use of uniform MDT (UMDT) that includes the same 3-drug regimen of MDT with the same duration of treatment (6 months) for all leprosy patients (PB and MB leprosy). For PB leprosy patients, there is evidence of better clinical outcomes with a 3-drug 6-month regimen compared with a 2-drug 6-month regimen. The problem of under-treatment due to miscategorization could be partly mitigated by the current recommendation to use a 3-drug regimen for PB leprosy. While for MB leprosy patients, evidence on potential benefits and harms of a shorter 3-drug 6-month regimen compared with a 3-drug 12-month regimen were limited and inconclusive. (WHO 2018). In addition, a recently published results of an RCT found a

3- drug 6-month regimen associated with an increased risk of relapse (Penna et al 2017).

In this study, male predominance was seen in both the study population ( 3.5 : 1 ) as well as among relapse cases ( 3 : 2 ). Men are more likely to get affected because of an increased exposure to infection by male sex. But this might also be related to the conventional delay in seeking healthcare and a lower access to health services for women in the ethnic area (Desikan 1997, John et al 2010). No conclusions could be drawn about gender differences related to health accessibility, health care seeking behaviour, and social discrimination.

It is known that the rate of relapse is governed by two factors; namely, the high initial bacterial load and the long period of follow-up (Girdhar et al 2000). The initial bacterial load before and at RFT is noted to be closely correlated to the risk of relapse. In the current study, most relapses 80% (8/10) were observed within 5 years after RFT showing early occurrence of the relapse, it is likely to be due to drug resistance or treatment failure, and less likely to be due to re-infection or the growth of persister organisms, which would be expected to occur in the late years of follow-up. Among these 8 relapses, four patients who had initial BI $\geqslant$5 relapsed within 2 years from RFT. Similarly in a study from Agra, higher no. of relapses were seen in patients with high BI ($\geqslant$ 4) patients in the fixed drug therapy group as well as long term treatment patients, relapses occurred within 4 years of stopping treatment (Girdhar et al 2000)

In another study of patients treated up till smear negativity, a higher relapse rate of 1.27 per 100 person years was observed among patients with an initial BI of $\geqslant$ 4.00+ as compared to 0.46 per 100 person years among patients with an initial BI of <4.00+ (Waters 1995). A definite increase in the BI is used as the main diagnosing criterion for diagnosing a relapse in MB leprosy, as it is the indicator for re-multiplying bacteria. Other diagnostic method for the prediction of relapse like elevated anti PGL-1 antibody levels may be easily available and could replace BI in future (Linder K et al 2008). In patients with higher BI, combined chemotherapy and immunotherapy should be considered as it helps in accelerated decline of BI as well as minimizing risk of relapse (Kaur et al 2002). One TT patient and one LL patient having initial BI 0 and 2.5 relapsed after 20 years and 15 years from RFT. Late occurrence of relapse after RFT underlines the importance of continued surveillance after RFT. Relapses may be either due to persisters or reinfection. In the absence of any method to prove reinfection, it is reasonable to assume that both the relapses reported are due to persisters ; however, reinfection in these patients cannot be ruled out.

Active community participation in all stages is the key element in the success or failure of a control programme. Intensive efforts to promote early detection, regular treatment and long term follow up will help in severing deformity and risk of relapse. In our study also, 19 out of 144 patients showed irregularity in treatment. Although, no one presented with relapse till the time of data analysis.

The present study showed that fixed drug therapy for especially for high BI patients may not be adequate in reducing the relapses. Combined chemo-immuno therapy should be considered in such cases ( Kaur et al 2002). Patients with high BI ($\geqslant$3+) should be put on surveillance for longer period and including

skin smears as a routine procedure in the follow-up examination. When long term follow up is not feasible, education of the patient to report soon after appearance of new skin lesions should be done. The problem of under-treatment due to miscategorization can be solved by the current recommendation to use a 3-drug regimen for PB leprosy ( Katoch et al 1999, WHO 2018). Relapsed cases of leprosy should be identified and put back on chemotherapy (or combined chemotherapy plus immunotherapy) as soon as possible to prevent further disability and transmission of infection. Being a tertiary care institution, our cohort had limitation of dominance of MB types, thus our results can not be extrapolated to all leprosy cases at community level.

WHO MDT therapy is a very acceptable and adequate treatment for the great majority of patients with low overall relapse rate. In contrast, our study showed higher relapse rate of 6.94%. However, a longer follow up involving a larger sample size is needed to have a better idea about the frequency and duration of follow up after RFT, treatment modifications for high risk groups and overall frequency of relapse cases.

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