Ind J Dermatol Venereol Leprol 1996; 62 : 33-5

FIXED DURATION MDT IN LEPROSY AND CLINICAL CURE

Paramjit Kaur*, Gurmohan Singh**

Fixed duration multi drug therapy has been found to be very effective in elimination of leprosy from public health point of view. This study was conducted to see its effectiveness so far as 'clinical cure' is concerned. One hundred consecutive patients attending a consultant's clinic were followed till a period of 6 months and 2 years in PB and MB cases of leprosy respectively. Sixty four percent of the total patients had 'clinical cure' at the end of prescribed treatment.

Key Words : Rifampicin, Clofazimine, Dapsone, Leprosy elimination

Introduction

It is now being increasingly accepted by the Public Health Leprologists and National Leprosy Eradication Programmes all over the world and by WHO that Fixed Duration (FD) treatment by multi drug therapy (MDT) in leprosy is very effective to eliminate leprosy as public health problem. Dermatologists who look after the individual cases of leprosy differ and find the 'clinical cure' does not occur after FD MDT in all the cases of leprosy.

The present study was conducted in 100 consecutive cases of leprosy treated with standard WHO recommended regimen.

This report discusses the outcome of these patients till the time of their being released from treatment.

Materials and Methods

One hundred consecutive cases of leprosy who reported for treatment at the private clinic of a dermatologist constituted the subjects of the study. After evaluation they were classified. The patients were put on MDT regimen according to the type of leprosy. Those who had reaction were given NSAIDs and/or systemic steroids according to severity of reactions. In cases with type II reaction, a higher dose of clofazimine ie, 100 mg to 200 mg per day was used till the reaction persisted. The patients were followed up regularly and complication if any developed was managed. Patients with deformity of recent onset were treated with long term corticosteroids.

Clinical examination was particularly directed towards the size of lesions, number of lesions, induration of lesions, extent of erythema, tenderness and thickness of nerves. They were called 'clinically cured' only if erythema and induration of lesions have disappeared; the nerves have become nontender and the size of lesions not increased.

Results

There were 64 males and 36 females in the study. The patients classified according to WHO for assigning treatment regimen showed that the 72 cases were MB and 28 were PB cases. Sixteen cases of the first group (MB cases) and 4 cases in the second group (PB cases) had reported with reaction of varying degree. Only 2 cases had type II reaction, the other 18 had type I reaction. Six of the reactional cases had early deformity. It involved ulnar nerve of one hand alone in 4 cases and in 2 cases alongwith partial foot drop.

*Professor of Epidemiology, Institute of Medical Sciences, **Consultant Leprologist and formerly Professor and Head of Dermatology, Venereology, Leprology, Institute of Medical Sciences, Banaras Hindu University, Varanasi-221005, India.

Address correspondence to : Prof Paramjit Kaur

The patients felt improved. The dermatologist's view was also satisfactory. The steroids when given were gradually withdrawn in 3 to 4 months time. The deformity started recovering within 2 months of start of treatment. These cases were continued with standard MDT for a period of 6 months.

Two patients developed fever after 2 months of starting treatment. It was neither associated with any worsening of old lesions nor appearance of new lesions. This would start 1½ to 2 hours after intake of rifampicin and would gradually rise to 101 to 104^0 F and then drop coming to normal in 8 to 10 hours. This was associated with joint and muscle pain in one case and without this in the second case. In the second case the fever had typical malaria like features due to intermittent rifampicin described by Kaur and Singh.[1] In both the cases rifampicin was stopped and instead pefloxacin (PROFLOX^R) was added in doses of 400 mg BD.

In one patient jaundice developed after 2½ months of institution of MDT. Whether it was infectious hepatitis or drug induced hepatitis was not studied. Treatment was stopped till liver function tests came to normal, after which treatment with dapsone, clofazimine and pefloxacin (PROFLOX^R) was started.

'Clinical cure' as defined in our methodology was seen only in 12 out of 28 PB cases and in 52 out of 72 MB cases. This shows that there is 64% cure rate as perceived by a dermatologist.

Thirty six of the patients needed further management whether as pharmacotherapy or suggestion therapy. Besides this another 12 out of 64 clinically cured patients were not satisfied as there still existed hypopigmentation etc which was explained. Five of the "clinically cured" patients were still bacteriologically positive and 7 MB cases were clinically still active but had become bacteriologically negative.

Discussion

MDT in leprosy is undoubtedly an important advancement to eliminate leprosy as public health problem, if the countries are able to implement it both in words and spirit. Unfortunately there has been so much false reporting, wrong diagnosis and poor follow up that it becomes difficult to accept most reports compiled country wise.

Many experienced dermatologists, who are the real consultants in the clinical aspects of the disease are sceptical about it, particularly FD MDT which is in vogue. This study was conducted in a small group of patients-a prototype of what consultant dermatologists get in their office practice.

We have defined 'clinical cure' as any clinician would expect and any patient would accept.

In the present study, 57% of the PB patients were clinically active at the end of 6 months FD MDT. Katoch et al[2] had 28% active cases left after 6 months of MDT. On follow up for another 6 months they could note an increase of inactivity rate by 4%, the others needed further treatment. Grugni et al[3] had 56 cases still active after 6 months of treatment. Pavithran[4] had also similar observations. In multibacillary cases one study showed that 28% cases had still clinical activity at the end of 2 years of regular MDT. One could expect that those patients who are nearer to the tuberculoid end of spectrum were likely to improve continuously after therapy. Those patients with high initial bacteriological index, have naturally a poor CMI and poor macrophage functioning, cannot be left alone after 2 years of treatment.

There is no evidence so far that MDT knocks down persisters.[5] Theoretically there is every reason to believe that in person with poor CMI, persisters are likely to grow and disease may relapse taking many years. It may take much longer than the incubation period of disease, since clofazimine still remains in tissues and continues to hold the growth of *M leprae*. A study[6] had shown a followup of 839 patients of MB type on treatment with WHO regimen of MDT. for 2½ to 5 years or more without any mention of patients dying, leaving the treatment or lost to follow-up, which makes a field study too good. A 100% compliance and followup for 5 years even in the best field studies is not possible.

This study does not in any way undermine the usefulness and effectiveness of FD MDT in leprosy in field conditions and in National Programmes, where the main objective is to reduce the quantum of infection. From the clinical dermatologists' point of view, who look after the ultimate needs of leprosy patients, this study highlights that proper assessment of cases is essential particularly in those who are not 'clinically cured' so that further management plan could be worked out. They cannot be left alone as 'cured'.

References

1. Singh G, Kaur V. Malaria-like fever with intermittent rifampicin. Ind J Dermatol Venereol Leprol 1993;59:304-5.
2. Katoch K, Rama G, Ramanathan U, Desikan KV. Comparison of three regimens containing rifampicin for treatment of paucibacillary leprosy patients. Int J Lep 1987; 55:1-8.
3. Grugni A, Nadkagni NJ, Kini MS. Multidrug therapy in paucibacillary leprosy-a five years experience. Ind J Lep 1988;60:589-92.
4. Pavithran K. Relapse of paucibacillary leprosy after short course multidrug therapy. Ind J Lep 1988; 60:225-29.
5. Waters MFR. Relapse following various types of multidrug therapy in multibacillary leprosy. Lep Rev 1995; 66:1-9.
6. Ganapati R, Pai R, Gandewar KL, et al. For how long should a multibacillary leprosy patient be treated? Ind J Lep 1989; 61:467-71.