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Comparison of Three Regimens Containing Rifampin for Treatment of Paucibacillary Leprosy Patients[1]

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Rifampin is a potent bactericidal antileprosy drug which acts on DNA-dependent RNA polymerase ([1]). A study group of the World Health Organization (WHO) has recommended its usage in combination with other drugs for the treatment of all types of leprosy ([2]). Besides taking care of the problem of primary dapsone resistance, such a combined drug therapy may also markedly shorten the duration of treatment required for leprosy. Nearly 70% of the leprosy cases in India are of the paucibacillary types in which the bacillary load is very low. The WHO Study Group has arbitrarily fixed a period of 6 months for treatment of these cases ([2]). This needs to be verified. Whether there is any additional benefit of brief, initial intensive therapy with rifampin for paucibacillary cases also needs to be studied. Such an intensive therapy has been recommended by the working group of the government of India for the treatment of multibacillary types ([12]).

The present study was undertaken to arrive at an optimum dosage schedule and duration of treatment of paucibacillary leprosy cases. Three types of therapeutic regimens were planned. Paucibacillary types of cases were selected using the same criteria as recommended by the WHO Study Group ([2]). The preliminary results on the comparative efficacy of three regimens have been reported earlier ([9]). The study has now been extended to include more patients in each group with a longer follow-up.

PATIENTS AND METHODS

Paucibacillary leprosy patients, including indeterminate (I), tuberculoid (TT), and borderline tuberculoid (BT) types who were bacteriologically negative or had a bacterial index (BI) of less than 2 on the Ridley scale, were studied; a total of 236 paucibacillary patients ranging in age between 20–55 years. Of these patients, 58 were females and 178 were males. A previous history of drug intake was ascertained in each case, and only those patients who had not been treated with antileprosy drugs were included in the study. In some cases where the history of drug in-

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take was doubtful, urine was examined for dapsone as an additional screening test. These patients were then given a thorough clinical examination. The skin lesions were marked on the body chart and areas of anesthesia were carefully mapped. Skin smears were made and examined for acid-fast bacilli (AFB). The patients were randomly allocated to one of the three regimens described below.

Regimen I (as recommended by WHO). Rifampin 600 mg once a month, supervised for 6 months. Dapsone 100 mg daily, unsupervised for 6 months. The treatment was stopped at the end of 6 months.

Regimen II. Rifampin 600 mg once a month, supervised for 6 months. Dapsone 100 mg daily, unsupervised for 1 year. The treatment was stopped at the end of 1 year.

Regimen III. Rifampin 600 mg daily, supervised for 7 days in the first month; subsequently rifampin 600 mg once a month, supervised for an additional 5 months. Dapsone 100 mg daily, unsupervised for 1 year. The patients were hospitalized for the initial 7 days for administration of the supervised doses of rifampin. The treatment was stopped at the end of 1 year. Those patients who refused admission for the initial 7 days of supervised treatment of Regimen III were reallocated randomly to either Regimen I or II for which hospitalization was not required.

The clinical progress of the disease was carefully recorded every month during therapy. After the termination of treatment, the patients of all three regimens were followed up with the administration of a placebo. They were called for examination every 3 months, or every month if the clinical condition warranted. Skin smears were repeated at the time of termination of therapy. During the follow-up period, skin smears were obtained from any active lesions. Nerves were carefully examined, and a thorough sensory and motor assessment was carried out as and when required. The patients have been kept under continued surveillance. The present report is based on the follow-up of most of the cases for a period of 1½ years.

The definitions of the terms used in the study are as follows:

Active lesions. An active lesion appears clinically as an infiltrated or erythematous plaque or macule. The surface of the lesion is rough and pebbly in the case of raised lesions ([3]).

Criteria. The following criteria were considered as definitive evidence of worsening of disease activity or increase in signs of activity: a) skin smears becoming positive or persistently remaining positive; b) renewed activity in old lesions, i.e., reappearance of erythema with infiltration in a previously subsided lesion; c) appearance of new lesions when most of the other lesions are clinically regressing; d) increase in the size of old lesions with flattening of part of or the entire margin of a lesion and an increase in size of the lesion from the flattened part of the margin.

Mitsuda test. The Mitsuda test was performed by injecting 0.1 ml of lepromin intradermally and taking the late reading 4 weeks after injection. It was regarded as a positive Mitsuda test when the intradermal nodule measured 5 mm or more in diameter.

Relapse. The reappearance of any signs of activity after an initial period of complete subsidence of clinical activity was considered a relapse.

Reactions. The term reaction in this study is used to denote: a) occurrence of erythema, infiltration, swelling, and tenderness in the entire lesion; b) appearance of new lesions with similar well-defined margins, erythema, and swelling in association with swelling, erythema, and tenderness in all other lesions. This is differentiated from signs of activity or worsening in that in reaction all the lesions are inflammed and are tender on palpation. These clinical findings are usually associated with tenderness in the nerves.

Inactivity index. Inactivity index is the ratio between the number of patients who have become inactive and the total number of patients who were active at the start of therapy ([10]).

RESULTS

The number and classification of patients treated by the different regimens is shown in Table 1. The disease status of the patients in the three regimens was comparable (Tables 1–4) except that the proportion of Mitsuda-positive cases was slightly higher in

TABLE 1. *Classification of patients by regimen.*

Patients[a]	Regimen		
	I	II	III
TT	19	13	10
BT	63	55	47
I	8	10	11
Total	90	78	68

[a] TT = tuberculoid; BT = borderline tuberculoid; I = indeterminate leprosy.

TABLE 2. *Lepromin (Mitsuda) responses of the patients*

	Regimen		
	I	II	III
Mitsuda positive	66 (92%)	55 (84%)	54 (84%)
Mitsuda negative	12 (8%)	10 (16%)	10 (16%)
Not done	12	13	4

Regimen I. As seen in Table 4, 25 patients (27.8%) in Regimen I remained active at the time of termination of therapy. In 18 of these patients, treatment had to be restarted because of an increase in the signs of activity after treatment was stopped. Details of these cases are given in Table 5. This increase in activity warranting restarting of therapy occurred after the lapse of different time periods, as detailed in Table 6.

Among the patients who worsened, it was found that in two patients their smears did not become negative at the end of 6 months of treatment and after stoppage of treatment, their BI increased from 1+ to 2+ (Ridley scale). Three patients who were smear negative at the completion of therapy showed occasional bacilli at different time intervals after stopping treatment. Two patients developed new lesions. In seven patients there was an increase in the size of the lesions, and in nine patients there was reactivation of old lesions after treatment was stopped. One patient developed a nerve abscess. Treatment had to be restarted in all of these patients. In 7 patients the disease regressed spontaneously without antileprosy drugs; 1 was TT and 6 were BT. Six cases were Mitsuda positive and one was negative. Thus, there was no clinical or immunological distinction between the cases who worsened and those who regressed spontaneously after treatment was stopped.

Three patients in Regimen I who became inactive at the end of the scheduled 6 months of therapy relapsed later (Table 7); two were BT and one was indeterminate. Two of them were Mitsuda positive.

Out of 78 patients in Regimen II, four (5.1%) showed evidence of active disease at the time of stoppage of treatment. Details of their clinical status is given in Table 8. Three of these patients were BT and one was TT. All of these patients' disease subsided without any antileprosy treatment. There were no relapses of these or other cases during the follow-up period.

Sixty-eight patients were studied in Regimen III. During the first 3 months of therapy, six patients showed evidence of reaction with increased size of some lesions and with increased erythema in all lesions. The new lesions which appeared were tender on palpation. This subsided with continuation of antileprosy treatment. At the end of therapy at 1 year, two patients remained clinically active (Table 9). One was TT and Mitsuda positive, and his signs of activity regressed spontaneously without any antileprosy treatment. The other was BT and Mitsuda positive, and some of his lesions showed erythema and infiltration at places. These signs have decreased but have not completely subsided in the 10 months of follow-up available. No additional antileprosy drugs have been given until the time of reporting. There was no case of relapse in this group.

DISCUSSION

The WHO Study Group has clearly defined the paucibacillary leprosy group for

TABLE 3. *Bacteriological positivity of patients in all regimens.*

	Regimen		
	I	II	III
Bacteriologically positive	20	16	16
Total patients	90	78	68
% Positive	22.2	20.5	23.5

TABLE 4. *Number of lesions and responses to therapy by regimen.*

Regimen	3 lesions			4 to 5 lesions			6 to 10 lesions			>10 lesions		
	Total	Regressed	Not regressed	Total	Regressed	Not regressed	Total	Regressed	Not regressed	Total	Regressed	Not regressed
I	23	15	8 (3)[a]	13	9	4 (2)	30	20	10 (2)	24	21	3
II	27	26	1 (1)	16	14	2 (2)	17	16	1 (1)	18	18	0
III	15	15	0	10	10	0	21	19	2 (2)	22	22	0

[a] Figures in parentheses denote patients who regressed subsequently without further antileprosy treatment.

purposes of multidrug therapy. Such patients comprise more than 70% of the leprosy cases in India. All paucibacillary patients need to be treated. The objective of the WHO Scientific Working Group in recommending a time duration for treatment is very logical since a long duration of treatment leads to increased numbers of dropouts and the ultimate ineffectivity of treatment. By adding rifampin to the treatment regimen, it is aimed to cut short the duration of treatment. We have, therefore, tried three regimens containing rifampin to see which regimen gives the maximum advantage and cost effectiveness. It was found that in Regimens II and III, with dapsone and pulsed rifampin, 94.9% and 97.1% of the patients became inactive within a period of 12 months. This is much faster than the rate of inactivity with dapsone alone.

In another study carried out in our institute, it was observed that with dapsone alone only 76.6% of the cases became inactive at the end of 12 months, and the remaining cases took another 6 months to become inactive ([5]). Ekambaram ([4]) has reported that in nonlepromatous cases with less than two patches it required 181 weeks for the disease to become inactive; in cases with 2 to 5 patches, it required 208 weeks. The findings of Vellut ([16]) showed that with 4 years of dapsone monotherapy only 50% of nonlepromatous cases became inactive.

Earlier workers showed a high percentage of relapses with monotherapy. Touw Langendijk and Naafs ([15]) have reported a 14% relapse rate in TT patients treated with dapsone alone for 1½ years. Jesudasan, *et al.* ([8]) studied relapse rates in paucibacillary patients on dapsone monotherapy and found a 3% relapse rate after 4 years of treatment. Girdhar, *et al.* ([5]) in a study of TT/BT cases on dapsone and dapsone plus steroids found relapses in 9 out of 96 patients treated for 6 to 18 months. However, in the present combined-drug therapy of Regimens II and III, no relapses occurred in the 1½-year period of follow-up after treatment was terminated.

TABLE 5. *Details of active Regimen I patients who worsened after treatment was stopped.*[a]

	No. of patients
Type of disease	
TT	3
BT	14
I	1
Lepromin (Mitsuda) status	
Positive	14
Negative	2
ND[b]	2
Signs of worsening after termination of therapy[c]	
Positive smears	
Remained positive	2
Changed from negative to positive	3
Increased activity in old lesions	9
Increase in size of lesions	7
Development of new lesions	2
Nerve abscess	1

[a] N = 18.
[b] ND = not done.
[c] More than one of these signs was seen in some of the patients.

TABLE 6. *Follow-up of Regimen I cases who remained active at the time of termination of therapy.*

Duration	Worsening of disease	Regressed without further treatment
3 mos.	6	—
>3–6 mos.	5	3
>6–9 mos.	4	3
>9–12 mos.	2	1
>1 yr	1	—

TABLE 7. *Details of clinical findings of relapsed cases in Regimen I.*

Case no.	Disease type	Lepromin status (Mitsuda)	Time interval when relapse was observed	BI
1	BT	Positive	7 mos.	Negative
2	Indeterminate	Positive	7 mos.	Negative
3	BT	ND	8 mos.	Negative

The WHO Study Group has recommended treatment of paucibacillary cases for only 6 months. In our earlier reported study in which all three of these regimens were studied, it was noted that 29.6%, 34.28%, and 36.9% of the cases remained active in Regimens I, II, and III, respectively, at the end of 6 months. This shows that the percentages of patients who become inactive by the end of 6 months are similar. In the present study, 27.8% of the cases were found to be active at the end of 6 months of treatment. It is therefore apparent that 6 months' therapy is inadequate in view of such a high proportion of cases remaining active. Revankar, *et al.* ([13]) have also shown that only 71% of a total of 423 paucibacillary patients (both treated and untreated) became inactive at the end of 6 months of multidrug treatment, which is comparable to our results.

The WHO has arbitrarily fixed 6 months as the period of treatment for paucibacillary cases based on two considerations: a) The maximum bacterial load in paucibacillary cases is only 10^6 organisms, and b) adequate cell-mediated immunity (CMI) in this type of patient should take care of organisms remaining after the 6-month period of treatment ([2]). In the first place, it is not indicated how the possible bacterial number in paucibacillary cases has been estimated. In a study of bacillemia in leprosy patients at this institute ([11, 14]) it has been reported that 10^3 bacilli/ml of blood are found in some of the BT cases. It is obvious, therefore, that at least in some of the paucibacillary cases a much higher bacillary load is present. With regard to the possibility of CMI being helpful in eliminating the bacilli, the present work has shown that response to treatment is not influenced by immunological status. It was seen that out of 66 Mitsuda-positive patients in Regimen I, 20 continued to have active disease despite therapy for the scheduled period of 6 months, 14 of whom had to be treated further and 6 regressed without further treatment (Table 5). In contrast, out of 12 Mitsuda-negative cases nine showed inactivation by the same therapy. Jesudasan and Christian ([7]) have suggested that lepromin-negative paucibacillary patients should be considered as multibacillary cases for treatment purposes. Our findings indicate that a lepromin reaction by itself should not be the criteria for deciding therapy. However, treatment for a minimum period of 12 months could be sufficient to cover all paucibacillary cases irrespective of their lepromin status.

It has been observed that 25 out of 90 Regimen I, 4 out of 78 Regimen II, and 2 out of 68 Regimen III cases remained active at the time treatment was stopped. Out of these, 7 Regimen I cases, all 4 of the Regimen II cases, and 1 of the Regimen III cases regressed spontaneously. The remaining 18 cases of Regimen I showed worsening of the disease during the follow-up period. It is to be noted that there was no difference in the clinical type or lepromin status of the pa-

TABLE 8. *Details of Regimen II patients who showed evidence of activity at the time of termination of therapy.*

Case no.	Disease type	Lepromin status (Mitsuda)	Time interval in which activity subsided without specific anti-leprosy treatment	BI
1	BT	Negative	4 mos.	Negative
2	TT	Positive	6 mos.	Negative
3	BT	Positive	3 mos.	Negative
4	BT	Positive	4 mos.	Negative

TABLE 9. *Detailed clinical status of Regimen II patients who showed evidence of activity at the time of termination of therapy.*

Case no.	Disease type	Lepromin status (Mitsuda)	Time interval in which activity subsided without specific antileprosy treatment	BI
1	TT	Positive	4 mos.	Negative
2	BT	Positive	Lesions subsiding but not completely subsided at 10 mos.	Negative

tients who subsided spontaneously and those who worsened.

The criteria for declaring the cases as worsened are: a) skin smears becoming positive or persistently remaining positive, b) appearance of new lesions, c) renewed activity in old lesions when most other lesions are clinically regressing, and d) an increase in the size of old lesions with flattening of part of or the entire margin of the lesion and an increase in the size of the lesion from the flattened part of the margin. One or more of the criteria would indicate worsening of the disease. We call these cases "continuation and worsening" of the disease and not "relapse" because the disease did not become inactive at any point in time. None of the patients showed any evidence of "reaction" during this worsening phase. As seen in Table 5, such worsening of the disease occurred in all the types of paucibacillary patients as well as in those with positive and negative lepromin and bacteriological status. All of these patients had to be restarted on antileprosy treatment. Jesudasan, *et al.* (6) recommended varying periods of treatment for lepromin-positive and lepromin-negative paucibacillary cases, depending upon the number of patches. Such a classification is cumbersome and not practical in mass therapy. The present study (Table 4) shows that paucibacillary types of cases, irrespective of the number of patches, would respond equally effectively if treatment is continued for 1 year.

It was found that the results with Regimens II and III were comparable. As such, the initial intensive therapy for 7 days with rifampin has not offered any special advantage.

As reported earlier, the responses to all three regimens were similar at the end of 6 months of starting treatment, the inactivity indices being 0.72 (Regimen I), 0.66 (Regimen II), and 0.64 (Regimen III). On the other hand, the inactivity indices were 0.76 (Regimen I), 0.94 (Regimen II), and 0.97 (Regimen III) at 12 months after initiation of the various drug regimens, as seen in Table 10. The differences in the inactive indices at 12 months are clearly due to discontinuing treatment at 6 months in Regimen I. Supplementing treatment with dapsone for another 6 months has achieved significantly better results. The bacteriological and clinical worsening which was seen in 18 out of 25 active cases in Regimen I was not encountered in any of the patients with Regimens II or III when they were continued on dapsone for another 6 months. Those few patients who had some residual activity at 12 months in Regimens II and III subsided spontaneously afterward. Further, in a limited period of follow-up of 1½ years, three relapses have been reported in Regimen I but no relapse has occurred in either Regimen II or Regimen III.

Our study thus shows that treatment for 6 months with dapsone and pulsed rifampin followed by further treatment for 6 months with dapsone alone would render paucibacillary leprosy inactive irrespective of the type of the disease, number of patches, or lepromin status. It is possible that even with a shorter period of treatment some of the cases might become inactive. However, it would be very difficult to predict by any

TABLE 10. *Inactivity indices of all three regimens studied.*

Inactivity index	Regimen		
	I	II	III
At end of 6 mos. of starting treatment	0.72	0.66	0.64
At end of 12 mos. of starting treatment	0.76	0.94	0.97

known criteria which of the cases would respond to such short-term therapy. It is, therefore, safe to treat all paucibacillary cases for a period of 12 months.

SUMMARY

Three regimens containing rifampin have been tried in paucibacillary leprosy patients. The patients were selected according to the criteria laid down by the World Health Organization (WHO). In Regimen I, rifampin 600 mg is given once a month for 6 months with dapsone 100 mg daily. Treatment is stopped at the end of 6 months. Regimen II is the same as Regimen I, and is supplemented with an additional 6 months' treatment with dapsone 100 mg daily. Regimen III is the same as Regimen II, except that rifampin is administered daily for the first 7 days.

At the end of the scheduled treatment period, 72.2% of the patients in Regimen I, 94.9% of the patients in Regimen II, and 97.1% in Regimen III became inactive. Eighteen out of the 25 active cases at the time Regimen I treatment was stopped had to be restarted on drug therapy since they showed a worsening of their disease, as indicated by an increase in their bacterial index, the appearance of new lesions, renewed activity in old lesions, an increase in the size of old lesions, or development of nerve abscesses. The remaining seven cases regressed without further treatment. All four Regimen II patients and two Regimen III patients who had evidence of activity at the time treatment was stopped did not require any further treatment. On follow-up for 1½ years, three Regimen I patients and none of the Regimen II or Regimen III patients showed relapses.

It is thus apparent that rifampin helps to shorten the time duration and to increase the cost effectiveness of treatment of paucibacillary leprosy cases. The criteria used for selection of patients by the WHO scientific group is well conceived and easily understood by all groups of workers engaged in treating such patients. However, 6 months' treatment appears to be inadequate, and supplementing it with 6 more months of treatment seems to be necessary. The present study shows that paucibacillary cases, irrespective of the number of patches, type of disease, and lepromin status, would respond equally effectively if treatment is continued for 1 year. An initial intensive therapy with rifampin does not seem to offer any additional advantage.

RESUMEN

Se ensayaron 3 esquemas de tratamiento con rifampina en pacientes con lepra paucibacilar. Los pacientes fueron seleccionados de acuerdo a los criterios de la Organización Mundial de la Salud (OMS). En el esquema I, se administraron 600 mg de rifampina una vez al mes durante 6 meses junto con 100 mg diarios de dapsona. El tratamiento se suspendió a los 6 meses. El esquema II fue el mismo que el esquema I pero estuvo adicionado de un tratamiento por 6 meses con 100 mg diarios de dapsona. El esquema III fue igual que el II excepto que la rifampina se administró diario durante los primeros 7 días.

Al final del período de cada esquema de tratamiento, el 72.2% de los pacientes en el esquema I, el 94.9% de los pacientes en el esquema II y el 97.1% en el esquema III resultaron inactivos. Diez y ocho de los 25 casos activos encontrados cuando se suspendió el tratamiento en el esquema I tuvieron que retomar la quimioterapia porque mostraron un agravamiento de su enfermedad (aumento en su índice bacteriano, aparición de nuevas lesiones, renovada actividad en lesiones viejas, incremento en el tamaño de lesiones viejas o desarrollo de abscesos en nervios). Los 7 casos restantes se recuperaron sin tratamiento adicional. Los 4 pacientes del esquema II y 2 pacientes del esquema III que tenían evidencias de actividad cuando se suspendió el tratamiento no necesitaron de ningún tratamiento adicional. Después de 1½ años de seguimiento, tres pacientes del esquema I y ninguno de los esquemas II ó III mostraron recaídas.

Es así aparente que la rifampina ayuda a acortar el tiempo de tratamiento y a incrementar su efectividad en los casos de lepra paucibacilares. Los criterios propuestos para la selección de pacientes por el grup científico de la OMS, están bien concebidos y son fácilmente entendibles por todos los grupos involucrados en el tratamiento de tales pacientes. Sin embargo, el tratamiento durante 6 meses parece inadecuado siendo necesario prolongarlo por 6 meses adicionales. Este estudio muestra que los casos paucibacilares, independientemente del número de manchas, tipo de enfermedad, y reactividad a la lepromina, podrían responder de manera igualmente efectiva si el tratamiento se continuara por 1 año. La terapia intensiva inicial con rifampina no parece ofrecer ninguna ventaja adicional.

RÉSUMÉ

On a essayé chez des malades atteints de lèpre paucibacillaire trois posologies différentes à base de rifampine. Les malades ont été sélectionnés selon les critères établis par l'Organisation Mondiale de la Santé (OMS).

Le Régime I a consisté en rifampine à raison de 600 mg une fois par mois pendant 6 mois, accompagnée de 100 mg de dapsone par jour. Le traitement a été interrompu à la fin des 6 mois. Le régime II était la même que la Posologie I, sinon qu'on y ajoutait 6 mois de traitement complémentaires par la dapsone à la dose de 100 mg quotidiennement. Le Régime III était la même que le Régime II, si ce n'est que de la rifampine a été administrée journellement pendant les 7 premiers jours.

A la fin de la période prévue pour le traitement, le nombre de malades devenus inactifs s'élevait respectivement à 72,2% avec le Régime I, 94,9% avec le Régime II, et 97,1% avec le Régime III. Parmi les 25 sujets qui présentaient une maladie encore active au moment où le Régime I a été arrêtée, dix-huit ont du être remis en traitement à la suite d'une aggravation de leur maladie, révélée par une augmentation de l'index bactérien, l'apparition de nouvelles lésions, une reprise d'activités des lésions anciennes, une augmentation de la dimension des anciennes lésions, ou le développement d'abcès au niveau des nerfs. Les sept autres cas ont présenté une poursuite de leur amélioration sans aucun traitement supplémentaire. Les quatre malades soumis au Régime II, et les deux malades auxquels on avait administré le Régime III, et qui présentaient encore des lésions actives au moment où le traitement avait été interrompu, n'ont ensuite requis aucun traitement supplémentaire. Lors d'un suivi mené un an et demi plus tard, trois des malades traités par le Régime I présentaient une récidive, mais les malades soumis aux Régimes II n'en présentaient aucune.

Il apparaît dès lors que la rifampine contribue à raccourcir la durée du traitement des cas de lèpre paucibacillaire, et augmente également le rapport coût-efficacité de ce traitement. Les critères définis par le groupe scientifique de l'OMS pour choisir les malades sont bien conçus; ils sont également bien compris par toutes les catégories de personnel qui sont responsables pour le traitement de ces malades. Néanmoins, un traitement limité à 6 mois apparaît inadéquat, et il semble nécessaire de le compléter par 6 mois supplémentaires. Cette étude montre que les cas paucibacillaires répondent bien, et d'une manière identique, lorsqu'on poursuit le traitement pour un an, et ceci sans égards au nombre de macules, au type de la maladie, et à la réponse à la lépromine. Une thérapeutique intensive initiale par la rifampine ne paraît pas présenter d'avantages supplémentaires.

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