Lepr Rev (1986) **57,** Supplement 3, 101–105

Preliminary evaluation of the effect of WHO–MDT on disabilities in leprosy patients in Malawi (Central Africa)

G BOERRIGTER* & J M PONNIGHAUS†
**LEPRA Control Project, P.O. Box 148, Lilongwe, Malawi;*
†*LEPRA Evaluation Project, P.O. Box 46, Chilumba, Malawi*

Introduction

Ideally, when introducing a new and supposedly improved treatment, this new regimen should first be tried out in a study group. The results in this study group should be compared with the results in a control group which continued to receive the old treatment. However WHO–MDT was generally introduced without waiting for the results of any such controlled trial on the assumption that (a) multidrug treatment would be superior to dapsone monotherapy, and that (b) there was no time for a controlled trial because resistance of *Mycobacterium leprae* to dapsone was globally reported to be developing into a serious threat to the effectiveness of leprosy control projects.[1] Thus unfortunately it is now only possible to evaluate WHO–MDT using historical controls treated with dapsone monotherapy.

WHO–MDT in paucibacilliferous patients should be evaluated in terms of: a, adverse drug reactions (including death attributable to the regimen); b, development or regression of disabilities; c, Type I reactions; d, relapses; and e, acceptability (compliance and operational feasibility).

All clinical parameters being equal, the cost per patient treated with WHO–MDT should also be compared with the cost per patient treated with dapsone monotherapy.

In this short paper we present a preliminary evaluation of WHO–MDT in paucibacilliferous patients in Malawi in terms of the development or regression of disabilities during and after treatment.

Methods

WHO–MDT in this paper means 600 mg rifampicin supervised intake at intervals

0305-7518/86/057101S+05 $01.00

of four or more weeks, plus 100 mg dapsone daily self-administered (for adults). Completion of treatment means that a patient has taken six supervised doses of rifampicin within nine months of registration.

As a historical control group we chose a previously analysed cohort of patients newly registered in 1975 in the Northern and the Central Region Leprosy Control Projects who, with few exceptions, received dapsone monotherapy.[2] They were generally discharged in accordance with the WHO guidelines in current use before the introduction of WHO–MDT.[2]

The study group consists of paucibacilliferous patients who were newly registered in 1983 in the entire LEPRA Control Project in Malawi. Thus the two groups do not refer to exactly the same parent population.

Treatment for Type-I reactions (delayed hypersensitivity reactions) was similar in both groups and consisted of 30 mg prednisolone daily, reduced by 5 mg every 2 weeks. All treatment was on an outpatient basis.

The disability grading used by the Leprosy Control Assistants in the field was the five grade system recommended by WHO in 1960 and no change has been made since 1973 in the use of this grading system in Malaŵi.[3] The single highest disability grade in a patient (attributable to leprosy) rather than the sum total of all disabilities, was used to determine the level of disability.

Results

The prevention of the development of disabilities is generally stated as one of the main objectives of a leprosy control project[4] and it therefore seems relevant to show in particular which percentage of newly registered patients developed new or higher levels of disabilities during or after completion of treatment.

Table 1 shows that of 831 new paucibacilliferous patients registered in 1983 and reviewed after completion of treatment, 31 patients (3·7%) either developed new disabilities (having grade 0 at registration) or that their disabilities worsened during WHO–MDT. So far, data are available for 545 patients who were due and available for review examination one year after completion of WHO–MDT. The percentage of patients with newly developed or worse disabilities since registration had increased to 5·7% by that time. Table 1 also shows that in 50% of those with disabilities at registration the level of disability decreased during and after WHO–MDT. The majority of these (57/75) regained sensitivity in hands or feet which had been anaesthetic at registration.

In the control group of 264 tuberculoid and borderline leprosy patients in the Northern Region and 262 patients in the Central Region Leprosy Control Projects review notes are only available for the point in time of discharge, since these individuals were not kept under active surveillance after completion of treatment. The review notes at discharge indicated that seven patients (2·7%) in the Northern and 16 patients (6·1%) in the Central Region had developed new

Table 1. Historical comparison of the development of disabilities during and after WHO–MDT with the development of disabilities during dapsone monotherapy in leprosy patients in Malawi (Central Africa).

	Control groups		Study group
	Northern Region LCP Tuberculoid and borderline leprosy, 1975 cohort	Central Region LCP Tuberculoid and borderline leprosy, 1975 cohort	LEPRA Control Project Malawi Paucibacilliferous patients registered in 1983
Number of patients registered	380	479	862
Percentage of patients with any disabilities at registration (WHO grading 1960, = or > 1) and with complete review notes at 'discharge' = completion of treatment	10·6% (29/264)	19·5% (51/262)	17·3% (144/831)
Percentage of patients with worse disabilities at 'discharge' (= completion of treatment) than at registration	2·7% (7/264)	6·1% (16/262)	3·7% (31*/831)
Percentage of patients with worse disabilities one year after 'discharge' (= completion of treatment) than at registration	—	—	5·7% (31*/545)
Percentage of patients with less disabilities at 'discharge' than at registration	27·6% (8/29)	19·6% (10/51)	52·1% (75/144)
Percentage of patients with less disabilities one year after 'discharge' than at registration	—	—	51·7% (46/89)

* not all the same individuals

disabilities during treatment or were found at discharge with disabilities worse than at registration. This range of 2·7–6·1% is likely to be representative for the outcome after many years of dapsone monotherapy in Malawi. In this control group eight out of 29 patients (27·6%) in the Northern and 10 out of 51 patients (19·6%) in the Central Region were found at discharge with a decrease in disabilities.

Discussion

Our comparison of the 1975 with the 1983 cohort in terms of disabilities would seem to be reasonably valid, because the organizational structure, diagnostic procedures and the assessment of disabilities did not change appreciably between 1975 and 1985 within the LEPRA Control Projects in Malaŵi. One indication for the comparability of the two groups is the similarity of the level of disability at registration which is particularly similar in the study group and the 1975 Central Region cohort of newly registered patients.

On the other hand there is only a partial overlap of the recruitment areas of the two groups and the 1975 cohort includes some patients with borderline leprosy, who, if registered in 1983, would perhaps not have been classified as paucibacilliferous patients. In addition, treatment for Type I reactions was probably more vigorously instituted in the eighties than in the seventies.[2] This last difference would lead one to expect a slightly better outcome in those patients registered in 1983 than in those registered in 1975.

Nevertheless our preliminary analysis presented here shows that the percentage of patients who developed new disabilities or experienced a deterioration in disabilities during or after WHO–MDT was within the range of such adverse outcomes seen in patients treated with dapsone monotherapy.

In fact, the outcome one year after completion of WHO–MDT (5·7% with new or worse disabilities) is remarkably similar to the outcome in the Central Region 1975 cohort which was unfavourable in 6·1% of patients at the end of at least 3 years dapsone monotherapy.

There seems to be some evidence however that a higher percentage of patients with potentially reversible disabilities improved during or after WHO–MDT than after dapsone monotherapy. One could speculate that this might be due to a swifter action of multidrug treatment in arresting the disease process and thus facilitating recovery of nerve function.

This aspect might warrant an investigation in a controlled trial since the methodology of using historical controls as in this analysis is an obviously crude and potentially misleading one.

Acknowledgment

We would like to thank LEPRA's National Manager, Rev. P Garland for having extracted data of the new paucibacilliferous leprosy patients registered in 1983 for us from the National Register.

References

[1] World Health Organization. Chemotherapy of leprosy for control programmes. *WHO Tech Report Series*, 1982; 675, 9–14.

[2] Boerrigter G, Ponnighaus JM. Ten years' leprosy control work in Malawi (Central Africa)—I, Methods and outcome after treatment. *Lepr Rev*, 1986; **57:** 199–219.
[3] World Health Organization. *WHO Tech Report Series*, 1960; 189.
[4] Robinson D. *Epidemiology and the Community control of disease in warm climate countries*. Edinburgh: Churchill-Livingstone, 1985: 206–222.