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SHORT REPORT

A multi-centre study on quality of routine data collection on relapses

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Summary
Objectives: To assess the quality of routine data collection on relapses in leprosy programmes in six countries.
Design: Through a questionnaire for project managers.
Results: The number of reported relapse cases did not correlate with number of new cases in the individual projects. Even where available, skin smears were not always used for diagnosis of MB cases and relapses. The diagnosis of relapses in the participating projects was exclusively on clinical basis – in 91.8% on the basis of new lesions.
Conclusion: Criteria for identification of relapses were not known or not applied in uniform manner in the projects involved in the research.

Introduction

Relapse rates are an important indicator of effectiveness of leprosy treatment and disease control measures,[1,2] and to evaluate the efficacy of new treatment regimens. Relapses may also be due to drug resistance.

Both multi-bacillary and paucibacillary leprosy patients have potential risk of relapse.[2] Relapses may be difficult to differentiate from reactions and trials with steroids may be necessary to differentiate between relapse and reactions.[3] The risk of relapse after completion of MDT may be greater among those patients who have a high bacterial index.[4] The majority of relapses occur in the first 5 years after completing treatment[5] and the annual risk of relapse does not increase over time, so that if the disease does not relapse within 5–6 years, then risk of relapse are negligible.[2]

This retrospective study assessed the quality of routine data on relapses in the period 1996–2001 in 15 projects in six countries (three in Asia – Bangladesh, China and India; and three in Africa – Comores islands, Ghana and Mozambique).

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Methodology

Fifteen projects in six countries supported by AIFO/Italy participated in this study by providing information on relapse cases registered in a determined area between January 1996 and June 2001. The questionnaires were sent to these projects in beginning of 2004 and the responses were collected during the same year. This data has only recently been compiled and analysed.

Findings from the Multi-centre Study

The 15 projects reported 7735 new cases in that period, six projects did not report any case of relapse and the remaining nine reported 145 relapse cases. The overall rate of relapse per new patient treated was 1·87%, and ranged from 0 to 29·4% in individual projects.

Detailed information was obtained for 109 cases of relapses whose initial diagnosis was 47 PB cases (43·1%), 54 MB cases (49·5%) and eight unknown (7·4%). Information on time of relapse, initial diagnosis (PB/MB) and treatment regimen used was available for 99 patients. Out of the 99 patients, 68 people received standard MDT treatment (68·7%) and 31 (31·3%) had received non-standard MDT treatments. The details are show in Table 1.

Fifty-five percent of people presented themselves at the health centre for diagnosis of the relapse, 29·7% of relapses were discovered during follow-up visits or during special campaigns like LEC, while in 18·3% of records this information was not available. Out of the 47 cases initially diagnosed as PB, 18 cases (38·3%) had a skin smear done, while the remaining 29 cases (61·7%) did not have any skin smear at the time of initial diagnosis. When these 47 patients were diagnosed at relapse, eight of them were again classified as PB cases and in six of them diagnosis was confirmed by skin smear (75%). The remaining 39 were diagnosed as MB and the diagnosis was confirmed by a skin smear in 31 cases (79·5%). Out of the 54 cases initially diagnosed as MB, 12 had a skin smear done at the time of first diagnosis (22·2%) while 42 cases (77·8%) did not have a skin smear taken. At relapse, all of them were diagnosed as MB and this diagnosis was confirmed by a skin smear in

Table 1. Information about 99 relapse cases: initial diagnosis and treatment, and the gap between treatment completion and relapse

Number of patients	PB/MB	Initial Treatment	Median gap in months (range)
43	PB	Standard MDT	39 (2 to 165)
3	PB	ROM	68 (15 – 78)
25	MB	Standard MDT	30 (4 – 186)
19	MB	ROMC 6 wks	88 (56 – 113)
8	MB	RED 52 wks	184·5 (148 – 228)
1	MB	Rifam mono. 10 wks	197

Notes: Standard MDT – WHO recommended MDT regimen given for at least 6 months for PB cases and at least 12 months for MB cases; ROM: single dose treatment with Rifampicine, Ofloxacine and Monocycline; ROMC – Rifampicine 600 mg, Ofloxacine 400 mg, Clofazimine 100 mg given once daily and Monocycline 100 mg once a week for a total of 6 weeks; RED: Rifampicine 600 mg, Ethionamide 375 mg & Dapsone 100 mg, daily for 52 weeks; Rifam mono: Monotherapy with Rifampicine 150 mg daily for 10 weeks.

41 cases (76%), while in the remaining 13 cases (24%), the diagnosis of relapse was on clinical grounds.

Out of the total of 109 cases, 100 cases (91·8%) were diagnosed as relapse because of the presence of new skin lesions, 37% also had exacerbations of old lesions, 2% had nerve tenderness, 5% had nerve enlargement and 6% had new deformities. In the remaining nine cases (8·2%), the diagnosis of relapse was made on the basis of – (a) exacerbation of old lesions with positive skin smear in five cases, (b) exacerbation of old lesions, nerve enlargement and positive skin smears in two cases, and (c) nerve enlargement accompanied with new disabilities in two cases. In no case of relapse included in this study was a biopsy for histopathological examination or other tests such as bacterial culture or PCR reported.

Out of the 109 cases of relapse included in this study, nine (8·2%) also had at least one episode of Type I reaction (reversal reaction) some time in the past, two people (1·8%) had at least one episode of Type II (ENL) reaction, 79 (72·6%) didn't have any reactions and for 19 (17·4%) no information was available.

Discussion

NATIONAL GUIDELINES ABOUT RELAPSES IN LEPROSY

Six projects did not report any relapses, one noted the case load was small but the others reported no clear explanation or definition of a relapse in the national guidelines of leprosy programme. This may be because of lack of clear definition of relapses in national guidelines or lack of awareness in the project staff about this definition.

USE OF SKIN SMEARS FOR DIAGNOSIS OF LEPROSY

Among the cases in which information about the first diagnosis was available, only 22% classified as MB had a skin smear test at the first diagnosis. At the time of the relapse, in the same projects, the percentage of patients undergoing a skin smear test increased to more than 75%. This means that even where skin smear facilities were available it was not used in a significant number of MB cases, to help in the confirmation of diagnosis.

CRITERIA FOR DIAGNOSING RELAPSES

Almost 92% of all the relapse cases were diagnosed on the basis of new lesions.

Conclusions

The multi-centre study involving 15 projects in six countries (three in Africa and three in Asia) shows that in some countries and projects there may not have been clear national guidelines about diagnosis of leprosy relapses. In countries and projects where guidelines about diagnosis of relapse existed, the differences among numbers of relapses in areas with similar case loads of leprosy suggest that the criteria for diagnosing relapse may not have been applied in a uniform manner. The standard criteria for the diagnosis of relapses are given in the Operational Guidelines[6] as the appearance of definite new lesions and/or an increase in the bacterial index of 2 or more at any single site.

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