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Modified Active Surveillance System (MASS); a novel clinicopathological evaluation of PB leprosy patients after RFT, in Mangalore, India

R. MANJUNATH, K. NARENDRA KAMATH, GANESH S. PAI, JEROME PINTO & VIMALA VINOD
Department of Skin & Sexually Transmitted Disease, Kasturba Medical College, Mangalore 575 001, India

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Summary The current recommendations for leprosy control programmes include stopping active surveillance in view of the very low relapse rates and a phased integration of leprosy services with the general health services. Passive surveillance may not be adequate, more so because of the introduction of newer, shorter drug regimens. This study is an effort to evolve a modified active surveillance, which is cost-effective, simple and also a novel substitute for the increased workload caused by the dwindling number of PMWS. One thousand one hundred RFT-PB leprosy patients were recalled for a review under the Modified Active Surveillance System (MASS), carried out over two phases. Patients were divided into groups as per the mode of response to the mailed postcards; Responders (patients who reported to the OPD in person), Untraceables (patients whose postcards returned back) and non-responders (patients who did not report to the OPD after receiving the mail). At the end of phase I, we had 120 Responders, 480 Untraceables and 500 Non-responders. In phase II, which began 2 months later, the 500 non-responders were dispatched reminders. In this phase, there were 31 responders, 60 untraceables and 409 non-responders. Thus, at the completion of phases I and II, there were 151 responders, 540 untraceables and 409 non-responders. Of the 151 patients examined, 71 had no complaints (category 1), 41 had fresh leprosy-related complaints (category IIA), 14 had fresh leprosy-unrelated complaints (category IIB) and 25 had persistence of old complaints (category III). Cumulative PYR of the 151 patients was 1155·42. Forty-one patients had fresh leprosy-related complaints. Skin biopsy was done in the 17 patients with fresh skin patches, of whom four showed histopathological evidence of relapse. Relapse rate in our study was 0·35/100 PYR. Mean duration after RFT at relapse was 4·9 years. Our scepticism towards passive surveillance systems is justified by these 41 patients with fresh leprosy-related complaints, who voluntarily reported only after receiving the postcards. We recommend the introduction of a phase III, wherein the services of PMWs may be used to contact the 409 patients who remained unresponsive at the completion of phases I and II. We also recommend the introduction of a universal format for recording addresses of all new patients,

Correspondence to: R. Manjunath, c/o Dr Ganesh S. Pai, DERMA-CARE, Trade Centre, Bunt's Hostel Road, Mangalore 575 001, India (e-mail: gspai@satyam.net.in)

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which would be of immense help in patient retrieval in all such surveillance systems in the future.

Introduction

Decline in the statistical parameters of leprosy due to the highly efficacious WHO-MDT has altered the disease scenario at the community level. Two of the current recommendations are bound to create significant changes in the functional modalities of leprosy programmes. They are:

1. Recommendation to stop active surveillance because of the very low risk of relapse.[1]
2. Integration of leprosy activities with the general health services because of the low prevalence at the community level.[2,3]

A passive surveillance system[4] is not entirely justifiable, especially in view of the newer, shorter, drug regimens.[5] Therefore, the current need is for modified active surveillance, which would be comprehensive, cost-effective and simple.

Our study focused on the evaluation of all RFT-PB cases spread over six urban leprosy centres (ULC) in the city of Mangalore. As a modification, the postman was a substitute for the paramedical worker (PMW), while patients were recalled to the OPD for review by mailing cost-effective postcards.

Dwindling fund resources and a likely reduction of field force are likely to disturb the existing surveillance systems. The postcard system should therefore be a good alternative.

Materials and methods

Our study aimed at evaluating PB leprosy patients after RFT, with an emphasis on detection of relapses.

The addresses of PB leprosy patients released from therapy in the last 20 years were collected from the RFT registers of the six ULCs of Mangalore City. Patients who had not completed 6 months after RFT were excluded.

One thousand one hundred RFT-PB leprosy patients were recalled for a review under the Modified Active Surveillance System (MASS), carried out over two phases. In the first phase, 120 patients had responded and 480 postcards were returned back, from which it was discovered that 290 patients had either moved away or were deceased and 190 patients had an inadequate postal addresses. Five hundred patients did not respond.

In the second phase, which began 2 months later, the 500 non-responders were sent reminders. Interestingly, 31 patients responded in person, 60 postcards were returned back citing the same reasons as in phase I and 409 patients still remained unresponsive.

In both phases, for the patients who responded, a comprehensive leprosy-related clinical evaluation was done. Relevant investigations, including skin biopsy, were performed when indicated. Of the 151 responders, 41 had fresh leprosy-related complaints, mainly nerve thickening and neurological deficit, and this group was evaluated by a neurologist. Nerve conduction studies were done in necessary cases.

The responders were placed in age cohorts of 10 years each. Five-year cohorts were done with respect to years since RFT, for a time trend analysis.

Criteria for relapse in our study was clinical (appearance of new lesions, renewed activity of the old lesions or evidence of new nerve function loss) with histological evidence of leprosy. Type 1 late reversal reaction was ruled out clinically and after a therapeutic challenge with oral corticosteroids administered over 2–4 weeks.[6]

The statistical guidelines used were according to person years at risk (PYR). Relapse rate is calculated using the formula:[7]

$$\text{Relapse rate/100 PYR} = \frac{\text{Number of relapses}}{\text{Cumulative PYR of all the patients evaluated}} \times 100$$

Observations and results

According to the mode of response to the mailed postcards, the patients were divided into three groups (Table 1); Responders, Untraceables and Non-responders. Responders were patients who reported in person for evaluation on receipt of the postcard. Untraceables were those where the mails returned back by the postal department. The reasons attributed to the return were that the patients were either deceased or had moved away or had a grossly inadequate address. Non-responders included those who received the mail but failed to respond.

The 151 patients who responded were divided into three categories (Table 2). Category I included those patients with no complaints. Category II included patients who had complete resolution of their leprosy lesions after therapy but subsequently developed fresh lesions. Patients with fresh leprosy-related complaints were included in category IIA. Some of these fresh lesions were unrelated to leprosy such as eczemas, vitiligo, chronic urticaria, *T. versicolor* and dermatophytoses. These dermatoses were segregated as category IIB. Category III patients included those who never had a complete resolution of their leprosy lesions, at any time after RFT.

Cohort analysis of the 151 cases studied with respect to the duration since RFT was: 28 cases (18·48%) in the last 5 years (between 1995 and 2000), 64 cases (42·24%) between the last 5 and 10 years (1990 to 1995), 53 cases (34·98%) between the last 10 and 15 years

Table 1. Observed mode of response

	Phase I	Phase II	Total
Total number of patients to whom postcards were mailed	1100	500**	1100
Responders (patients who reported to the OPD in person)	120	31	151
Untraceables (patients whose postcards returned back)	480	60	540
• Patient deceased/moved away	290	60	350
• Inadequate postal addresses	190	–	190
Non-responders (patients who did not report to the OPD after receiving the postcard)	500	409	409

**These 500 are the same non-responders at the end of phase I.

Table 2. Categories of patients who responded

	Phase I	Phase II	Total
Category I Patients with no complaints	55 (440·24)*	16 (128·01)	71 (568·25)
Category II Patients with fresh complaints	43 (372·06)	12 (84·96)	55 (457·02)
IIA Related to the disease	34 (300·80)	7 (51·13)	41 (351·93)
II B Unrelated to the disease	9 (71·26)	5 (33·83)	14 (105·09)
Category III Patients with persistent old complaints	22 (121·16)	3 (8·99)	25 (130·15)
Grand total	120 (933·46)	31 (221·96)	151 (1155·42)

*Figures in brackets are the cumulative PYR** of each category.
**PYR = Person Years at Risk = Date of relapse/clinical evaluation—Date of RFT
Cumulative PYR of a group = Sum of all the individual PYR.

(1985 to 1990) and six cases (3·96%) between the last 15 and 20 years (1980 to 1985) (Figure 1).

By age, the cases were classified as 10-year cohorts. There were 40 cases (31·35%) in the 7–20 years age group, 39 cases (25·74%) in the 21–30 years age group, 21 cases (13·86%) in the 31–40 years age group, 15 cases (9·9%) in the 51–60 years age group, nine cases (5·94%) between 61 and 70 years and one patient (0·66%) aged 85 years (Figure 2).

Forty-one patients had fresh leprosy-related complaints [category IIA (Table 3)]. Of these, 17 had new skin lesions, of which 11 were associated with nerve thickening. Histopathological evidence of leprosy in the form of granulomas composed of epitheloid cells, lymphocytes and Langhan's giant cells infiltrating dermal nerves and other adnexa were detected in four cases.

Past recording of neurological involvement was inadequate, as it was often carried out by PMWs in field conditions. Current evaluation revealed tingling/numbness (24 patients), footdrop (three patients), weakness (eight patients), nerve thickening (11 patients) and trophic ulcers (three patients) (Table 3). These patients belonged to category IIA. This

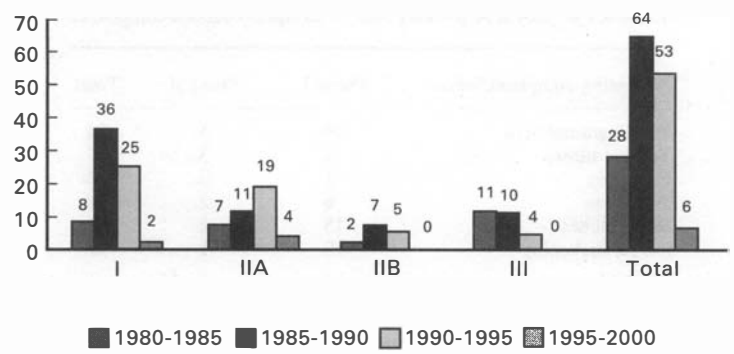

Figure 1. Cohort analysis of cases studied with respect to duration since RFT.

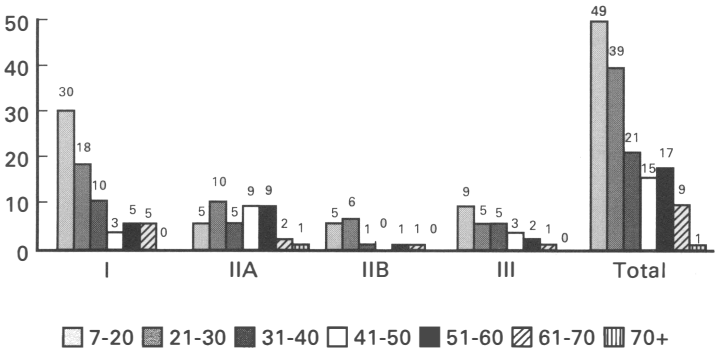

Figure 2. Classification of cases by age.

group of 41 patients with fresh leprosy-related complaints was evaluated by a neurologist and nerve conduction studies were also done. Significant reduction in velocity of propagation was observed in all the cases. Of these, only four cases showed histopathological evidence on multiple biopsies.

These four patients were labelled as biopsy proven relapses (Table 4) as per our criteria. The other 13 patients were labelled as suspected relapses, and are under observation.

Rate of relapse in our study was 0·35/100 PYR.

Mean duration at relapse was 4·9 years after RFT.

Discussion

In 1998, more than 500,000 new cases were reported in India, which accounted for 69% of the global incidence.[8] A problem of this magnitude certainly calls for effective resource utilization towards newer case detection.

The magnitude of community health problems posed by undetected relapses far exceeds the picture reflected by the low number of detected relapses. In our study, we have 41 patients with fresh onset leprosy-related complaints after RFT (Table 3). None of these patients had

Table 3. Category II A: patients with fresh leprosy-related complaints

Presenting complaint/lesion	Phase I	Phase II	Total
Tingling/numbness	19	5	24
Trophic ulcers	4	3	7
Foot drop	1	2	3
Weakness	6	2	8
Skin patches	15	2	17
Nerve thickening	10	1	11
Total*	34	7	41

*Figures shown in 'Total' indicate the total number of patients and not the sum of all the individual complaints, due to the presence of multiple complaints in some patients.

Table 4. Biopsy proven relapses

Patient Age(yrs)/sex	Duration after RFT at relapse	Past therapy	Type of relapse
47/M	1 year 4 months	MDT	TT
38/M	5 year 7 months	MDT	BT
60/M	11 year 10 months	MDT	BT
24/F	1 year 1 month	MDT	BT

voluntarily reported before getting a reminder in the form of a postcard. This justifies our scepticism towards passive surveillance systems relying upon patient awareness and self-reporting.

The large number of non-responders (409 patients) is the major drawback in this form of MASS. This is probably because the patients are daily wage earners and would not visit the hospital as they have no fresh complaints. Reinforcing their attitude is the counselling of patients at the time of RFT, when they are told that they are free from the disease.

Hence we propose the introduction of a phase III, wherein the services of paramedical workers are to be used to trace the non-responders. The onus of the total dependability on PMWs for surveillance needs to be reviewed in the future scenario of a gradual phasing out of leprosy programmes. Our system should reduce the workload for an already overburdened workforce. The reduction in surveillance costs achieved by our study had become necessary as most of the NGO funds are being diverted to programmes on HIV and malaria.

We also recommend the introduction of a universal format for recording the present and permanent addresses of all new patients. This step will further increase the patient response in such modified active surveillance methods in future.

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