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Practical problems in the management of leprosy

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Summary The categorization of leprosy into paucibacillary or multibacillary depends on the report of slit-skin smears. Unfortunately, in many control programmes the quality of slit smears is below par. Taking the example of India, the main reasons were that the work of laboratory technicians was unrewarding as compared to serving in a general health care system. There was lack of equipment and an unrealistic patient to technician ratio. Future attempts were made by experienced workers to devise a clinical system for classifying leprosy as paucibacillary or multibacillary based on counting the number of lesions. However this method did not prove cost-effective because more paucibacillary patients were classified in the multibacillary group increasing the burden of treatment. A renewed attempt to improve slit-smear performance should be made by modifying the existing methods. This can definitely improve the situation. Patients with multiple macular lesions and those with neuritic leprosy are best treated with the MB–MDT regimen. The treatment for PB leprosy is to continue up to 6 months but in MB leprosy with a high bacterial index a longer duration of MDT may be required. Following completion of MDT many cases with deformity are accumulating and their care forms are a neglected part of many control programmes. In addition to strengthening the infrastructure, simple techniques must be imparted to those with deformities and disabilities. This involves the artful and innovative cooperation of the health worker, patient and the community. The leprosy worker should be motivated to promote such activities.

The introduction of multidrug therapy (MDT) in leprosy was recommended in 1982.[1] This has paid rich dividends to a disease where many aspects of therapy were unclear. It was a turning point in the strategy of leprosy control and it brought a uniform approach in the treatment of the disease. Within a few years the standard regimens were accepted and many of the control programmes were streamlined. The most visible achievement following the implementation of MDT was the drop in prevalence rate of the disease. India, the biggest country in South-East Asia shared this achievement and the effective

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caseload came down from 4 million leprosy cases in the year 1981 to 0·94 million by the end of March 1994.[2] These developments generated optimism among all personnel actively involved in the eradication of leprosy. At the same time it also brought to the fore some practical problems which need to be discussed on the basis of the accumulated experience and newer findings. These issues are:

Classification

The categorization of leprosy into paucibacillary (PB) and multibacillary (MB) for the purpose of MDT is based on a mathematical estimation of the bacterial population in the tissue[1] and depends on the report of slit-skin smears. In the widely used Ridley–Jopling classification, PB leprosy includes indeterminate (I), tuberculoid (TT) and borderline–tuberculoid (BT) with a bacterial index (BI) <2 (Ridley scale) at any site; MB leprosy includes midborderline (BB), borderline–lepromatous (BL) and lepromatous (LL) with a BI of 2 or more at any site. The distinction between PB and MB required the services of an equipped skin-smear laboratory. Contrary to this expectation, the performance of skin-smear laboratories has not been satisfactory except for those in selected institutions managed by government and nongovernment organizations catering to a limited population.[1,3–6] Attention to the low standard of performance of slit-skin smear laboratories had also been drawn by the WHO Expert Committee as early as 1977.[7] Following the recommendation of MDT in 1982[1] many countries attempted to organize their skin-smear services in their control programmes. Some of the centres also tried to evolve a system of quality control and cross-checking,[5,8,9] but inspite of these efforts the laboratory services did not improve to a satisfactory level. India runs one of the largest organized control programmes with an inbuilt evaluation system. It has been seen in independent evaluations that a significant number of the posts for laboratory technicians remained vacant and only 40% of the registered cases had skin-smear examination,[10] a situation that continued to prevail.[11] While commenting on the poor standard of laboratory services, some of the causative factors were also enumerated by the evaluating teams. These indicated that working in skin-smear laboratories has been less attractive for the technicians. They preferred to work in a general health care system as it was more rewarding than the monotonous and wearisome reporting of skin-smears.[3,5] Unrealistic patient to technician ratio and paucity of reagents and equipments had also added to their disinterest. Since most of the supervisory staff were not confident in skin-smear techniques, they failed to impart the necessary guidance. To address these shortcomings in the system the leprosy control programme in India,[12] from the very beginning of implementation of MDT, had advocated that all skin-smear positive patients be treated as MB leprosy irrespective of their classification. This compromise was later recommended by the WHO.[13]

At the end of almost a decade, the cumulative reports left an impression that the bacteriological services relating to slit-skin smears were less likely to improve. So in order to facilitate wider and speedy implementation of MDT, many in the Indian programme felt it necessary to categorize leprosy as PB or MB based on only clinical features, where both skin and nerve involvement were counted as separate lesions. This approach of bypassing smear examination is not exclusive to the Indian programme. Studies from Ethiopia[14], Nepal[15] and Bangladesh[16] showed that using only clinical

criteria more patients were classified as MB leprosy thus increasing the cost of treatment. This was similar to the Indian system[17] which advocated 10 or >10 lesions to be MB leprosy irrespective of the smear report. Improving the quality of skin-smear examination significantly reduced this overclassification.[18] We endorse the view that to make the programme cost-effective it is unwise to completely dispense with slit-smear examination. Fresh attempts should be made to improve the laboratory functioning by a more realistic and liberal approach to the problem. The decision to treat all skin-smear positive patients with MB–MDT is a welcome step in this regard.[12,13] Inadequately equipped peripheral laboratories can be closed and a district laboratory should be maintained to provide reliable service in doubtful situations.[3] Other suggestions[13,16] for maintaining a laboratory with reduced workload include taking smears from only three sites in MB leprosy, one earlobe and two active skin lesions, and in PB leprosy with a solitary skin lesion from its active edges at sites diametrically opposite to each other. Follow-up slit smears should be made from the site showing highest density of bacilli on initial examination.[19] Repeat skin smears from PB cases should be dispensed with. The morale of the technicians can be maintained by improving the system and making them feel an integral part of it.

The classification of macular lesions has also remained tenuous. Special mention has been made for careful consideration of these patients.[12,13] The fact that all determinate cases have a macular and an infiltrative stage is well known. The indeterminate cases by their early nature and the macular tuberculoid (or maculoanaesthetic) by virtue of better resistance have good prognosis. They are therefore to be considered as PB leprosy. The others with multiple macular lesions show the clinical features of borderline leprosy but biopsy and slit-skin smears are often not helpful. Histopathology shows either nonspecific lymphocytic infiltration[20] or a branching granuloma too small to produce induration. In the natural course these lesions eventually progress to the indurated forms of borderline leprosy.[21,22] Hence such patients should be taken as MB leprosy and given the appropriate MDT regimen. However it should also be borne in mind that the macular stage may represent the subsided or healed plaque forms of leprosy where the disease is inactive. A proper history and examination of previous records would bear this out.

The grouping of primary or pure neuritic leprosy is also not clear. With a high incidence of 17·7% of all leprosy cases in India[23] it accorded a separate category in the Indian system of classification and has been placed in the PB group.[12] However, it is really a grouping of all types of leprosy where due to lack of reliable indicators,[13] no distinction between PB and MB is made. So far as deformity is concerned it is more likely to occur in neuritic leprosy and a wrong decision in treatment can add to the risk.[24] Neuritic leprosy is perceived clinically as an insensitive area over the skin, muscle weakness, or tingling sensation, with or without nerve thickening and tenderness. Skin smears are of no use in neuritic leprosy and performing nerve biopsies are impractical. In some, neural signs may be an early manifestation and skin lesions can appear after a prolonged period,[25] sometimes even during therapy.[26] Though pure neuritic leprosy with a strong lepromin reaction similar to tuberculoid disease has been observed, the majority show borderline features in the nerve on histopathology.[27,28] Studies on patients with both skin and nerve lesions have often reported a higher bacillary load in the nerves as compared to the skin,[15,29,30] indicating that in clinical classification systems the definition of nerve involvement needs more elucidation.[13] The nerve lesions can neither be visualized nor expressed numerically except by naming the affected nerve(s) individually.

In our experience when skin lesions developed in some neuritic patients during therapy, they usually conformed to the borderline macular group. Hence, for the benefit of the patients and the ease of field staff it is reasonable to treat patients of neuritic leprosy with the MB-MDT regimen.

Length of treatment

The recommendation of the WHO Study Group[1] is to treat PB leprosy with MDT regimen using 2 drugs—rifampicin and dapsone for 6 months, and MB leprosy with three drugs comprising rifampicin, clofazimine and dapsone for 2 years or whenever possible upto smear negativity. Adequate therapy implied that a patient of PB leprosy has received 6 monthly doses of combined therapy within 9 months, and in the case of MB leprosy 24 monthly doses of combined therapy within 36 months.[31] Using a fixed duration of MDT for 6 months in histopathologically proven PB cases it was found that 40% still showed clinical signs of activity.[32] An additional 6 months' treatment with dapsone in PB patients with 4 to 9 lesions enhanced the disappearance of clinical signs of activity[33] and reduced the risk of relapse.[34] Nevertheless, the recent WHO Expert Committee[35] on the basis of available data pooled from other areas reiterated that the 6-month WHO-MDT regimen is adequate and should continue. In their opinion clearance of the lesions was related more to the individual's immune response and would gradually follow.

The treatment of MB leprosy has been reviewed in detail and it appears that the 2-year MDT regimen using three antileprosy drugs is effective but in patients with a higher initial BI a longer duration of treatment up to 4 years may be required[36] to diminish the chance of relapse. Such patients had registered a better fall in BI when immunotherapy with a vaccine was added to the WHO-MDT regimen[37] indicating a longer duration of therapy to achieve the same result when only MDT was administered. This approach has to be further evaluated in large scale field trials to assess its efficacy on other important issues like relapse.

Deformity and disability

Deformities and disabilities are the sequelae that persist even if the patient ceases to be a case of leprosy as defined by the WHO.[13] Though MDT implementation in India cured a large number of cases, a considerable number with leprosy-related impairments are accumulating. The extent of overall grade 2 deformity amounts to 15% of the total active and discharged cases.[38] An approximately equal percentage of leprosy affected persons also have grade 1 deformity. An independent survey in 19 SIDA supported districts revealed an increase in the deformity rate when both the old and new cases were included though there was a fall of 62·5% in the new cases.[39] In one district in South India in which the MDT programme was in operation for a period of 7 years, 98% of 2500 persons with leprosy-related disability have been declared cured.[40] They outnumber those under treatment. These observations indicate the formidable post-MDT residual problem in India. The infrastructure of the eradication programme in India has the provision of one physiotherapy technician for each control unit catering to a

population of about 4 lakhs. Different independent evaluation reports expressed poor deformity care in the control units.[10,11] Many physiotherapy technicians' posts remained vacant and out of these available only 50% of their time was utilized in disability care.[41] Undoubtedly, commendable support is being rendered by a limited number of voluntary and government organizations in the following areas. Reconstructive surgery facility with a fulltime surgeon is available in as many as 10 institutions. Visiting surgeons periodically operate in another 20 centres. Microcellular footwear is prepared and distributed in 11 centres and half a dozen centres are providing vocational rehabilitation.[38] But all facilities taken together are inadequate to meet the requirement, and there is need for a newer approach.

The last WHO expert committee on leprosy has for the first time acknowledged in its report that the leprosy programme is as much a patient care programme as it is a public health programme. Accordingly the government of India is in the process of launching measures to contain deformities and disabilities and to rehabilitate dehabilitated patients. In addition it is also being realized now that disability prevention rests primarily on the efforts of affected persons themselves and they need to be told simple techniques by which they can protect their anaesthetic parts and prevent worsening of impairments.[40] Due to the decrease of active cases in districts where the vertical programme is in operation for more than 5 years attempts are being made to deploy the leprosy workers as trainers for the patients. A workshop sponsored by the DANLEP recommended a composite approach involving the health workers, patients and the community.[42] This can be achieved by social action having complementary roles for these three groups. The leprosy staff will be acting as the trainers and motivators for such activities and continue their support as consultant when the affected persons approach them with special problems. This approach is already being practised in some of the centres in DANLEP-assisted MDT districts. In these centres one often witnesses camps where a large number of persons with leprosy-related impairments are engaged in oil massages, active and passive exercises, and hydro-oleotherapy. The community members support these camps with food, shelter, medicines and other utility items. Side by side a diagnostic camp also operates to detect new cases. All these constitute a package of treatment, deformity care and health education services. Spread of such movements will be of much help in preventing disabilities.

Conclusion

Classifying leprosy on the basis of clinical criteria will help in brining more cases under MDT. However the clinical picture can vary from place to place. For instance LL with few skin lesions were common in Bangladesh.[18] In such situations grouping on clinical findings alone can be deceptive. A reorganized supporting skin-smear laboratory as proposed must continue to assist the programme. Regarding length of treatment, 6 doses of MDT for PB is to continue with the hope that the residual granuloma will clear in the course of time. The MB cases with high BI need a longer duration of MDT. Services rendered for the prevention of deformity are inadequate. New strategies in which the patients will be taught the skill of taking care of their impairments with the leprosy worker acting as a trainer are being developed and practised in limited centres of the country. These practices need to be expanded.

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