

Prevention of Disabilities and Rehabilitation

1. Introduction

Leprosy results in a wide range of impairments, the most important of which is damage to peripheral nerves. Damage to peripheral nerves causes loss of sensory, motor and autonomic nerve function to the affected region, leading in turn to deformity, secondary deformity resulting from repeated trauma to as well as dryness and cracking of the skin, and inability to perform important activities of daily living. These consequences of nerve damage have an impact on the quality of life of those affected by the disease and also generate stigma. Societal attitudes towards those affected by leprosy, often based on religious, traditional and cultural beliefs, may limit participation of people affected by leprosy in their own communities. Prevention of impairment is therefore a high priority in the management of leprosy. Prevention of nerve damage and the management of impairments are important components of any leprosy program. Rehabilitation in leprosy should be fully integrated within existing community-based rehabilitation programs on an equal basis as those with disabilities due to other causes.

1.1 Prevention of Disability

Approaches to prevention and treatment of nerve damage, as well as to limiting secondary effects, such as the increasing deformity caused by trauma, are now a standard part of all leprosy programs. Guidance on the prevention of impairments and management of nerve damage is included in publications from the World Health Organization (1, 2) and ILEP (3-5), and in most national guidelines on leprosy control. The components of prevention of impairments in leprosy programs include measurement of impairment, detection and treatment of reactions, self-care, footwear and eye-care. The most commonly used measurement of impairments is the WHO Disability Index (6), which has been in use for several decades. It is robust and simple to use as an indicator of early case-detection. However, it is not responsive to change over time, and

has limited value in monitoring the progress of individual patients. Ball-point pens are frequently used in the field by health workers to assess sensation. Other approaches to assessment of nerve function, based on voluntary motor testing (7) and sensory testing using monofilaments (8), are more appropriate for monitoring the progress of individual patients. Most guidelines describe how to detect and treat reactions.

Detection of reactions is based on acute changes of the skin lesions and deterioration of nerve function; reactions are treated by fixed-dose steroid regimens. Self-care routines are taught, and patients are empowered to develop daily routines for inspection of limbs with sensory and motor impairment for signs of injury or infection, treatment of injuries, active and passive exercises to prevent joint stiffness, and soaking and oiling to minimize drying of the skin. Instruction on protective clothing, adapted tools, and the use of footwear is also provided. Recommendations on footwear are provided, aimed usually at individuals with sensory impairment of the plantar surface of the foot. Earlier documents stressed the design and characteristics of specialized footwear with cushioned insoles; however, more recent recommendations are for cheap, available and locally acceptable footwear. The sensory and motor impairments that affect the eyes, combined with the inflammatory processes of iridocyclitis, render the eye potentially vulnerable in leprosy. Examination of the eyes is recommended, as well as protection and lubrication.

1.2 Rehabilitation

Surgery plays an important role in the correction of deformities and in reconstructive procedures to improve function. Surgical correction of foot-drop and lagophthalmos can prevent secondary impairments such as ulceration and deformity of the foot and corneal scarring. Case-selection for reconstructive surgery is very important. Physiotherapy support is essential both pre- and post-surgery, as are facilities for occupational retraining. In the past, re-

habilitation in leprosy has tended to be physically oriented and isolated from general and community-based approaches to rehabilitation. This is now changing, as more integrated approaches are adopted, and better linkages to existing community-based and community-oriented rehabilitation are established. More recently, social and economic rehabilitation have been advocated.

2. The Evidence-basis for Prevention of Impairments and Rehabilitation

Guidelines for preventing and managing nerve function impairments (NFI) and for rehabilitation have been based largely on the experiences of individuals and programs. This section focuses on a systematic review and critical appraisal of the evidence for the effectiveness of specific aspects of prevention and treatment of impairments, and rehabilitation. The following four key questions, which were selected by discussion within the organizing group and by consultation with those in the field, are identified as priorities:

- Is early detection of leprosy, followed by prompt initiation of MDT, effective in prevention of impairments?
- Does early detection and treatment of reactions and new nerve damage prevent impairments? If so, what are the best methods of detection and the thresholds for treatment?
- Does steroid prophylaxis prevent impairment?
- How effective are interventions in self-care, provision of footwear and socioeconomic rehabilitation?

2.1 Is early detection of leprosy, followed by prompt initiation of MDT, effective in prevention of impairments?

Many publications assume that early diagnosis of leprosy and treatment with effective chemotherapy will prevent nerve damage^(9, 10). That early diagnosis of leprosy, prior to the development of NFI, and treatment with effective chemotherapy that interrupts the disease process prevents nerve damage appears plausible. However, the process of nerve involvement in leprosy may commence long before the disease is clinically manifest. Moreover, NFI occurs

before diagnosis, during MDT and after completion of MDT^(11, 12), either as a gradual process or as part of a reactional episode. Therefore, it is important to appraise critically the evidence that early detection and MDT is effective in preventing NFI, and to estimate the magnitude of such an effect.

The evidence may be based only on observational data, because it would be unethical to withhold effective chemotherapy in a controlled study of intervention. Trials of chemotherapy regimens could provide an opportunity to examine possible differences of impact on nerve function; regimens that include clofazimine may result in fewer episodes of reaction. To date, however, few chemotherapy trials have included nerve function as an outcome. Current trials may include nerve function as an outcome, but any difference of effect is likely to be small, compared to the differences between treatment and untreated control groups. It is important that trials of different chemotherapies for leprosy include nerve function as an outcome.

Observational data on the occurrence of NFI before, during and after MDT have been used to estimate the magnitude of the potential effect of early diagnosis and MDT on NFI. Using such data, a study in Bangladesh⁽¹²⁾ estimated that early detection and initiation of MDT could prevent more than three quarters of impairments, whereas efforts to prevent disability employed during and after MDT could prevent only one quarter. This estimate is based on a number of assumptions regarding the effectiveness of MDT and the frequency of impairments expected in untreated leprosy. Nevertheless, the study provided an estimate of the magnitude of the effect, and demonstrated that it may not be possible to prevent all impairments by MDT. Failure to achieve early detection limits the potential of MDT to prevent NFI.

In Ethiopia, it was shown⁽¹³⁾ that, as late as 10 years after MDT, one-third of patients never developed impairments. However, this study, which was conducted among a group of MDT-treated patients, of whom 55% were found to have impairments at diagnosis, raises the question of whether all patients would develop NFI if left untreated. There were 39 episodes of neuropathy

thy per 100 person years in the first year after commencing MDT in this AMFES cohort (14). In the BANDS cohort in Bangladesh 2.6% of PB cases and 37% of MB cases developed new nerve function impairment in the 2 years following detection and MDT treatment (15). A series of estimates (16) of the potential impact of implementing MDT on disability in leprosy have been attempted, based on a number of assumptions.

Recommendations.

- Early diagnosis of leprosy and treatment with MDT are recommended to reduce the frequency of NFI. This recommendation is supported by observational studies and estimates, and on a number of assumptions (such as that untreated cases would develop NFI).
- It should be noted, however, that MDT will not prevent all NFI, and that the magnitude of the impact is dependent on “early” case-detection and treatment.
- Nerve function should be included as an outcome measure in trials of leprosy chemotherapy.

2.2 Does early detection and treatment of reactions and new nerve damage prevent impairments? If so, what are the best methods of detection and the thresholds for treatment?

A recent review suggests that, overall, 60 per cent of patients treated with steroids regain nerve function (17), and a number of studies that assess the effectiveness of steroids in terms of recovery in NFI show recovery rates of a similar magnitude (18–20). Surgical inventions such as nerve decompression have been considered. Two trials of steroids *vs.* steroids *plus* surgical nerve decompression showed no added benefit of surgical intervention (21,22) in terms of nerve function. Larger, well-designed, controlled studies of early surgical interventions are indicated.

Defining early detection is difficult: “early” may be considered in terms of the duration of the history of symptoms and signs. However, studies also consider the severity of the presenting signs and symptoms in terms of the magnitude of the change of nerve function. A study in Nepal, based on a retrospective cohort design,

demonstrated the outcome to be related to the severity of nerve damage at diagnosis, which may itself be related to timeliness of detection (19). A pilot study demonstrated benefit from steroid therapy even when administered 6 months after onset of NFI (23). An important controlled trial that addresses early detection using monofilaments as part of the TRIPOD trials (24), showed that detection of early change in nerve function by monofilaments did not result in any additional benefit over detection based on careful use of a ball-point pen to assess sensory change.

2.2.1 Methods of early detection. The need for early detection and the development of more sensitive diagnostic methods for early detection of neuritis has been recognized (25). Because of a lack of consensus on the best methods, a study was conducted to assess five different methods (26): two weights of monofilaments, pinprick, temperature sensation, and palpation of nerve thickness. The study reported that the two best methods were palpation of nerve thickening and the 0.2 mg monofilament.

Predicting NFI and reactions is another approach to early detection. A review of the literature on type 1 reaction identified as risk factors BCG, pregnancy, and MDT (27). The review also attempted to estimate the proportion of disability that may be prevented by early detection and treatment of reactions. Facial skin lesions have also been identified as a potential risk factor for facial nerve damage, carrying almost a ten-fold greater risk (28). Previous nerve damage and MB classification were found to be very strong predictors of nerve damage and reactions in a large cohort study in Bangladesh, which suggested a prediction rule that could be used in the field (15). Analysis from the AMFES (29) cohort in Ethiopia suggested that nerve function should be assessed by standardized methods every month.

Serological tests have also been proposed as a method of predicting nerve damage and reactions. Anti PGL-I antibodies were not found to be predictive (30), whereas serum levels of neopterin may be an indicator (31). This possibility must be tested in large, prospective studies.

2.2.2 Threshold for treatment. The threshold for commencing steroid therapy in early reactions or NFI may be based on

the magnitude of the change of function or the duration of the change. NFI is not always associated with skin signs or symptoms of neuritis, such as pain or tingling in so-called silent neuropathy⁽³²⁾. Thus, reliance on symptoms and self-reporting is not sufficient. It must also be recognized that there is a degree of variation of nerve function assessment among methods and among observers using the same methods^(8, 33). A threshold for treatment based on change of nerve function must be higher than the expected variation in nerve function assessment.

Recommendations.

- Steroids are recommended to treat reactions and nerve function impairments of recent onset; the expected recovery rate for nerve function is approximately 60%.
- MB patients and those with existing nerve function impairments should be carefully monitored for new nerve function loss, as they are the groups at greatest risk.
- Assessment of nerve function using standard methods every month during MDT is recommended.
- Research is recommended to identify the optimal steroid regimen, to develop alternative and more effective treatments for reactions and recent nerve function loss, and to determine nerve function change thresholds for treatment.

2.3 Does steroid prophylaxis prevent impairment?

Steroids represent the accepted method⁽¹⁹⁾ of medically treating NFI and reactions in leprosy. However, would steroids, if given prophylactically along with MDT, prevent NFI and reactions⁽³⁴⁾? A number of studies that have investigated this question have recently been reviewed⁽³⁵⁾.

The results of two trials of steroid prophylaxis have been published. A small (150 participants) randomized trial, conducted in India and reported⁽³⁶⁾ in 1985, showed that 10 mg of a steroid administered daily along with chemotherapy for one month was effective in preventing nerve damage in PB patients. The second, an open controlled trial conducted in Bangladesh⁽³⁵⁾, also showed a significant beneficial effect of 20 mg prednisolone daily for 3 months. Both

studies suggest that such an intervention may prevent NFI and reactions.

A large scale, double-blind trial of low-dose prophylactic steroids, has been conducted in Bangladesh and Nepal^(24, 37). The dosage of prednisolone, 20 mg daily for the first three months, was tapered during the fourth month. Patients with previously untreated MB leprosy were randomly allocated to steroids or placebo along with MDT. The preliminary report⁽³⁸⁾ of the results of this trial, presented at the ILA Congress in Agra in 2000, confirmed a significant beneficial effect at 4 months, but the effect at 12 months follow-up was no longer statistically significant.

Recommendations. Further research is recommended on the use of prophylactic steroids in preventing NFI. It is not only important to demonstrate, by means of a randomized, double-blind controlled trial, that steroid prophylaxis is effective in preventing nerve damage, but also that the benefits outweigh the costs, including those of adverse reactions to steroids. The results of the trial should also indicate the magnitude of the effect, and whether the effect varies among identifiable subgroups.

2.4 How effective are interventions in self-care and provision of footwear?

Interventions to promote self-care among people with NFI, to provide protective footwear, and to stimulate socio-economic rehabilitation have become standard parts of leprosy programs over the last few decades. This section provides a review of the evidence for the effectiveness of each of these components. In practice, the components are usually delivered in an integrated manner. Some of the evidence addresses single components, whereas other evidence evaluates the effectiveness of packages of interventions.

2.4.1 Self-care. Self-care is the management, on a daily basis, of the effects of nerve function impairment, and is the responsibility of the individual. Many papers describe self-care, but do not evaluate its effectiveness. The role of health-care workers is to educate and enable patients in the self-care process. A major survey⁽⁴⁾ of self-care activities in ILEP-supported projects

in 1995 revealed that 90 per cent or more of projects train patients in self-care and give advice on footwear.

Four papers that evaluate self-care and an additional five that evaluate self-care and footwear together have been identified. Seven of these studies are based on before-and-after study designs, and two employ a comparison group. The four studies that evaluate only the self-care component are the following. First, a study conducted in India⁽³⁹⁾ demonstrated that a self-care intervention for a period of 4 months improved the quality of the skin, and considerably reduced both hand and plantar ulceration. The second study, a before-and-after study also conducted in India⁽⁴⁰⁾, showed physical, functional and social improvement after self-care, as assessed by the patients themselves. The third study, a controlled trial in which two different approaches (patient education and community education) to self-care were compared to a control group⁽⁴¹⁾, also demonstrated benefit. Conducted in Nepal, the fourth study⁽⁴²⁾, which was a comparative trial of a 14-day self-care training program, showed that those trained were significantly less likely to be admitted for an infected plantar ulcer than were the controls. Each of these four studies showed benefit from self-care; the two comparative trials, in which the two interventions were compared to a control group, provided more robust evidence.

2.4.2 Footwear. The importance of appropriate footwear for feet lacking plantar sensation was recognized in the 1950s and 1960s. The use of adapted and modified footwear, using both molded shoes and insoles cushioned with micro-cellular rubber, was advocated. However, this approach was criticized because such footwear is difficult to produce and because of stigma⁽⁴³⁻⁴⁵⁾. Treatment centers were unable to produce sufficient shoes for those who needed footwear, and, because the shoes were fragile, to repair and to replace them. Also, because the shoes were also obviously different from that worn by the rest of the community, they became a symbol of the disease. During the last decade, this approach has been superseded by one of encouraging appropriate, locally acceptable footwear.

Three studies evaluate footwear pro-

grams, five evaluate combined programs of self-care and footwear, and one evaluates footwear and socio-economic rehabilitation. The first study, a before-and-after investigation of footwear, was conducted in Ethiopia⁽⁴⁶⁾. The second, a trial of foot orthoses in India⁽⁴⁷⁾, demonstrated a large difference in impairments between the intervention group and the control group (58% versus 14%). The third trial is a randomized, controlled trial of different footwear conducted in Ethiopia⁽⁴⁸⁾ that also demonstrated benefit; this study demonstrated that canvas shoes with cushioned insoles were both cost-effective and acceptable.

Recommendations.

- Teaching and empowering patients in self-care is an effective activity, which should be part of all leprosy programs.
- Use of locally acceptable, appropriate footwear is a cost-effective intervention for those with loss of plantar sensation.

2.5 Socio-economic rehabilitation

Many of the earlier initiatives in rehabilitation focused on physical approaches. That the importance of social and economic aspects of rehabilitation is now being emphasized is evidenced by the recently produced guidelines for socio-economic rehabilitation^(49, 50). Most publications describe examples or case-studies in socio-economic rehabilitation. Two studies that describe an evaluation of such an approach were conducted in India. The first reported⁽⁵¹⁾ benefits from restoration of social and economic status. The second was an evaluation of a community-based rehabilitation initiative⁽⁵²⁾. Both studies stress the importance of participation of the client as well as involvement of the family and the community.

Self-care, footwear and rehabilitation activities are often combined within a program. Six published studies, all of which employed before-and-after designs, represent evaluations of the effectiveness of combined programs, and one considers a footwear and loan program. The six studies analyzing self-care and footwear programs were conducted in China^(53, 54), India⁽⁵⁵⁾, and Senegal⁽⁵⁶⁻⁵⁸⁾. The footwear and loan project was based in Chad⁽⁵⁹⁾. The two

studies in China showed beneficial effects, the study in India showed a 50% reduction of plantar ulcers, and the studies in Senegal showed improvement of between 33 and 62 per cent. The study of loans also reported a beneficial outcome.

Recommendations.

- Socio-economic rehabilitation, which requires participation by client, family and the community, is valuable for selected patients.
- Socio-economic rehabilitation for those affected by leprosy are best delivered through general community based rehabilitation programmes.

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