

Progress of Impairment Scores Following Commencement of Chemotherapy in Multibacillary Leprosy Patients¹

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Deformity and disability—the inability to perform activities of daily living—are major outcome “measures” of interest for leprosy patients. It has, therefore, been suggested that “disability” indicators should be used to monitor and evaluate progress in leprosy control (^{11, 17, 18}). This paper uses the terms “impairment” and “disability” as defined in the World Health Organization’s (WHO) publication International Classification of Impairments, Disabilities and Handicaps (ICIDH) (²⁵). We will, therefore, refer to the “WHO disability grade” as the “WHO impairment grade.”

It is only when disabilities are understood from a functional point of view, which is relevant to the patient, and in their relationship to impairments that more appropriate disability prevention programs can be initiated. A study is being carried out in our Leprosy Control Project (LCP) in West Nepal to find any associations between impairments and disabilities in leprosy patients. To get some baseline information, a retrospective study was undertaken of WHO impairment grades of a large number of field patients. In particular, the progress of those impairment grades over time after the patients had started chemotherapy was reviewed.

Study questions. 1. In what ways do WHO impairment grades of leprosy patients progress over time following commencement of chemotherapy? 2. How does that differ for patients without impairment at the commencement of treatment compared with those already impaired? 3. Does age, sex and type of leprosy affect the progress mentioned in 1?

SUBJECTS AND METHODS

A record review was done of all multibacillary (MB) patients registered between 1980 and 1993 and already released from treatment (RFT) at nine mobile clinic treatment centers in the Western Region. Case finding has been based on voluntary reporting. The diagnosis “leprosy” was made by experienced paramedical field staff. The MB/PB classification was based only on clinical criteria and skin smears as described previously (²⁰). The ballpoint pen method was used to test sensibility at 10 sites on the palm of the hand and 10 on the sole of the foot. From each patient card, the following information was collected: registration and RFT dates, age, sex, leprosy type, WHO impairment grades at diagnosis and any other recording at yearly intervals. The WHO grading used in these clinics was either the 4-point scale introduced in 1970 (²³) or the 3-point scale introduced in 1988 (²⁴). When the former grading was used, it was recoded to the 1988 format by grouping the grades “2” and “3” together as “2” (= visible deformity). In the case of impairment, the former grade 3 (severe visual impairment) became the new grade 2.

Statistical methods. To assess the progress of the impairment status of our study patients over time, an impairment

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TABLE 1. Characteristics of the 1082 MB patients whose records were reviewed for this study.

Variable	Follow up at 2 yrs.		No follow up		Total	p Value
	No.	%	No.	%		
Age	Mean	39.0	38.4			0.52 ^a
Sex						
Females	197	59.9	132	40.1	329	
Males	502	67.7	239	32.3	741	0.042 ^b
Not recorded	7		5		12	
Total	706	65.2	376	34.8	1082	
Classification						
I ^c	4	66.7	2	33.3	6	
BT	307	66.5	155	33.5	462	
BB	22	61.1	14	38.7	36	0.50 ^b
BL	171	69.0	77	31.0	248	
LL	114	62.6	68	37.4	182	
PN ^d	27	55.1	22	44.9	49	
Not recorded	61		38		99	
Total	706		376		1082	
Maximum WHO impairment grade at diagnosis						
0	310	64.7	168	35.1	478	
1	188	67.1	92	32.9	280	0.73 ^b
2	208	64.2	116	35.8	324	
Total	706		376		1082	
Median EHF ^e score after 1 year	0			0		0.45 ^f

^a Student's *t* test.

^b Chi-squared test.

^c Indeterminate, but later found to have a positive skin smear.

^d PN = Pure neuritic leprosy.

^e Sum of WHO impairment grades of both eyes, both hands and both feet.

^f Mann-Whitney *U* test.

sum score was employed. We used essentially the same score as de Rijk, *et al.* (⁴), but included eye impairment as well. The sum score is thus the sum of the WHO impairment grades of both eyes, hands and feet (EHF score: minimum 0 = no impairment; maximum 12 = visible deformity of both hands and feet, and severe bilateral impairment. The EHF score was calculated at diagnosis and for annual follow-up examinations which the patient had attended. To assess whether the patient had improved, stayed the same, or deteriorated, the difference in EHF scores between diagnosis and annual follow ups was calculated. A positive difference score was called "improvement," a score of zero was "stable," and a negative score was "deterioration."

We decided to use the data after 2 years as the main outcome measure because the proportion of patients lost to follow up increased dramatically beyond this. At 2

years, a sample of 706 remained (64.3%). The association between a three-category (deteriorated, stable, improved) outcome at 2 years and the explanatory variables was examined using 3 × N tables. Logistic regression was used to look at the joint effect of the explanatory variables on the outcome (³). For this purpose, the outcome was divided into only two categories, "deteriorated" and "stable or improved." The odds ratios (OR) obtained show the increase in risk of becoming more impaired when a patient belongs to a certain category, compared with those in the baseline category. The 95% confidence intervals (95% CI) for the OR are given. If these do not include 1, then the association is significant at the 5% level.

RESULTS

The mean age of the study subjects at diagnosis was 38.7 years. Seven-hundred-

TABLE 2. Univariate analysis of the association between age and the impairment status after 2-year follow up in 706 MB patients registered in field clinics in the Western Region, Nepal.

Variable	Impairment worse ^a		Stable		Improved		Total
	No.	%	No.	%	No.	%	
Age							
0-19	7	10.0	48	68.6	15	21.4	70
20-39	34	12.4	174	63.3	67	24.4	275
40-59	53	19.1	139	50.2	85	30.7	277
≥ 60	17	22.7	33	44	25	33.3	75
Not recorded	1	11.1	5	55.6	3	33.3	9
Total	112	15.9	399	56.5	195	27.6	706

^a Impairment worse = EHF score after 2 years higher than the EHF score at diagnosis; Stable = EHF score remained the same; Improved = EHF score after 2 years less than the EHF score at diagnosis.

forty-one patients were males (68.5%). Table 1 shows the distribution of the study patients into two groups, according to whether they had a 2-year follow-up record or not. The two groups were not significantly different, except for a larger proportion of females among those who did not have a follow up. Even after 1 year, the median impairment status (EHF score) of both groups was not significantly different. Of the 1082 patients, 478 (44.2%) had no impairment (a score of 0) at diagnosis. This left 55.8% of the patients scoring 1 or more.

Seven-hundred-six patients had an impairment grade recorded at the 2-year follow-up examination. Among these patients, 310 (43.9%) had no impairment at diagnosis. Two years after the start of leprosy treatment, the number without impairment had increased to 396/706 (56.1%). Therefore, it appeared that about 12% of

the patients had improved during this period. However, although this was the net result, the real situation was more complicated. Of 310/706 patients without initial impairment, 31 (10%) had developed some impairment after 2 years (Fig. 1). Of the 396 who had impairment at diagnosis, 195 (49.2%) improved, 120 (30.3%) remained stable, and 81 (20.5%) deteriorated (Fig. 2).

Impairment after 2 years and age. Table 2 shows that both the proportions of patients who deteriorated and who improved increased with age. This trend was (with our study size) not statistically significant for "deterioration" when the joint effects of age, sex, classification and initial impairment status were examined (Table 6). For "improvement," the trend completely changed in the multivariate model, with older age groups being less likely to im-

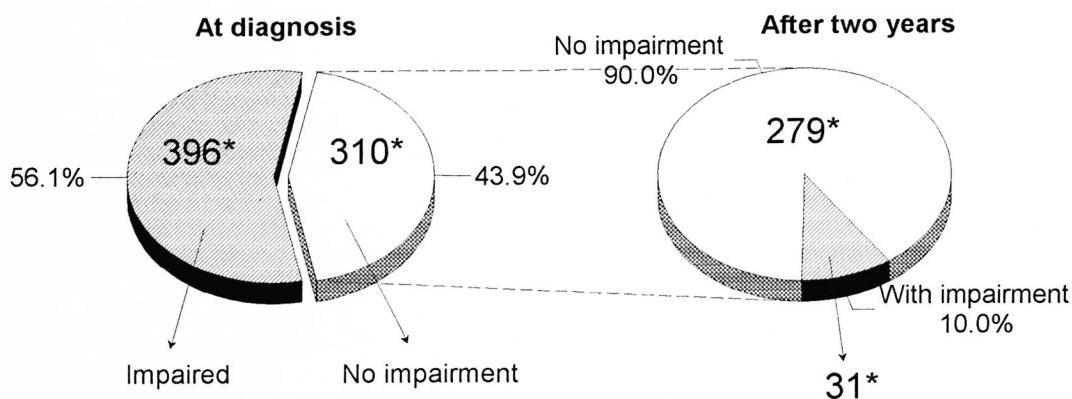


FIG. 1. Changes in impairment status during a 2-year period in MB patients without initial impairment (N = 310) in the Western Region of Nepal. * = number of patients in each category.

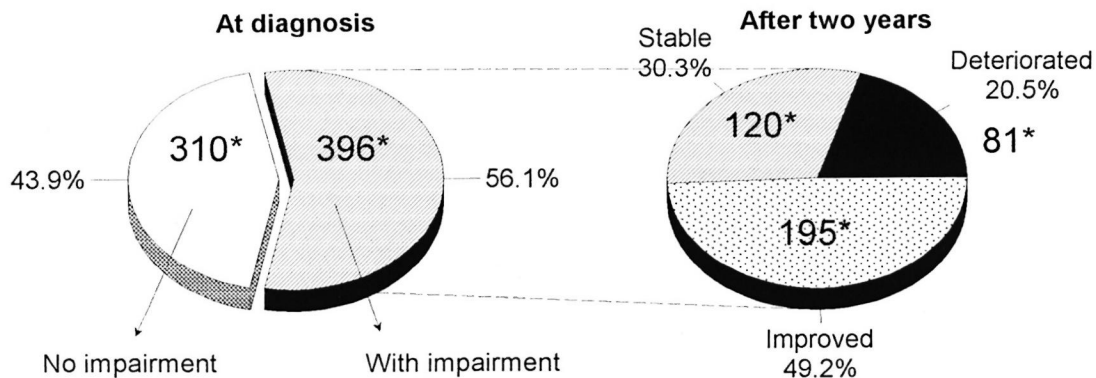


FIG. 2. Changes in impairment status during a 2-year period in MB patients with impairment at diagnosis (N = 396) in the Western Region of Nepal. * = number of patients in each category.

prove than those in the under-20 group (data not shown).

Impairment after 2 years and sex. Table 3 shows that there was little difference between males and females in the progress of impairment after 2 years.

Impairment after 2 years and classification. There were no significant differences in improvement or deterioration among the three patient groups (BT, BL, LL) which had sufficient numbers to make comparisons (Table 4).

Impairment after 2 years and initial impairment grade. Table 5 shows that the risk of developing new impairment was double for those who already had some impairment at diagnosis (grades 1 and 2 combined) compared with those who had no impairment (20.5% vs 10%, OR 2.05, 95% CI 1.4–3.0, $p = 0.0002$). An important observation was that the increased risk was about equal for those who only had sensory impairment at diagnosis and for those who

already had some visible deformity (adjusted OR 1.87 and 1.98, respectively; Table 6).

DISCUSSION

Few investigators have reported on the incidence of impairment^(9, 12, 14) or changes in impairment status over time^(13, 16). In the current study we examined the changes in impairment status that occurred during 2 years of MDT (a few patients were initially treated with dapsone) in a cohort of MB patients. The study was retrospective and was not free from the weaknesses inherent to such a design. Because all MB cases RFT during the afore-mentioned years were included, the results should at least be representative for MB patients at the given clinics. The main problem concerns loss to follow up. At 2 years, 35.7% of the patients had been lost as far as recording of impairment status was concerned. However, a de-

TABLE 3. Univariate analysis of the association between sex and the impairment status after 2-year follow up in 706 MB patients registered in field clinics in the Western Region, Nepal.

Variable	Impairment worse ^a		Stable		Improved		Total
	No.	%	No.	%	No.	%	
Sex							
Males	81	16.1	276	55.0	145	28.9	502
Females	30	15.2	119	60.4	48	24.4	197
Not recorded	1	14.3	4	57.1	2	28.6	7
Total	112	15.9	399	56.5	195	27.6	706

^a Impairment worse = EHF score after 2 years higher than the EHF score at diagnosis; Stable = EHF score remained the same; Improved = EHF score after 2 years less than the EHF score at diagnosis.

TABLE 4. *Univariate analysis of the association between classification and the impairment status after 2-year follow up in 706 MB patients registered in field clinics in the Western Region, Nepal.*

Variable	Impairment worse ^a		Stable		Improved		Total
	No.	%	No.	%	No.	%	
Classification							
I	1	25.0	2	50.0	1	25.0	4
BT	49	16.0	184	59.9	74	24.1	307
BB	2	9.1	14	63.6	6	27.3	22
BL	25	14.6	84	49.1	62	36.3	171
LL	14	12.3	66	57.9	34	29.8	114
PN ^b	7	25.9	13	48.2	7	25.9	27
Not recorded	14	23.0	36	59.0	11	18.0	61
Total	112	15.9	399	56.5	195	27.6	706

^a Impairment worse = EHF score after 2 years higher than the EHF score at diagnosis; Stable = EHF score remained the same; Improved = EHF score after 2 years less than the EHF score at diagnosis.

^b Pure neuritic leprosy.

tailed comparison of those with and those without a recording at 2 years revealed no differences between the two groups, except that fewer women had a follow-up examination (Table 1). This difference was, although significant at the 5% level, not large (40.1% of women vs 32.3% of men not having a follow-up exam). It is unlikely that the higher dropout rate among women was directly associated with their impairment status; rather, it reflects the greater difficulty experienced by women in Nepal to attend the health services, particularly for prolonged periods. We concluded that, despite the loss to follow up, the remaining sample could still be considered representative of the whole study group.

Prevalence. Among our study patients 56% had some impairment at diagnosis. During a recent survey among newly detected cases in East Nepal, this proportion was 64.1% (¹⁵). In Ethiopia, the proportion

of new MB patients with impairment was very similar—56.4% (⁴). In a cohort of MB patients in Malawi, only 34.1% had “disability at diagnosis” (¹³). The lower prevalence in Malawi seems to be at least partly due to a much lower reported prevalence of grade 1 (sensory impairment); 12.1%, compared with 26.9% in East Nepal, 32.3% in Ethiopia and 25.9% in the current study.

Incidence and risk factors. Smith, *et al.* (¹⁷) state that the realistic component of “disability” in their patient study population reversible by surgery and health education would be 8.3%. In contrast to this, our results show that 49.2% of our patients who were impaired at diagnosis actually improved (Fig. 2). Possible explanations for this observation are the effect of corticosteroid treatment, spontaneous recovery, the effect of surgery and ulcer care during hospital referral and, finally, the possibility of error. It is noted that this study was retro-

TABLE 5. *Univariate analysis of the association between initial impairment grade and the impairment status after 2-year follow up in 706 MB patients registered in field clinics in the Western Region, Nepal.*

Variable	Impairment worse ^a		Stable		Improved		Total
	No.	%	No.	%	No.	%	
Maximum grade ^b							
0	31	10.0	279	90.0			310
1	36	19.2	40	21.3	112	59.6	188
2	45	21.6	80	38.5	83	39.9	208
Total	112	15.9	399	56.5	195	27.6	706

^a Impairment worse = EHF score after 2 years higher than the EHF score at diagnosis; Stable = EHF score remained the same; Improved = EHF score after 2 years less than the EHF score at diagnosis.

^b Maximum WHO impairment grade at diagnosis.

TABLE 6. *Multivariate analysis of the association between impairment status after 2-year follow up (new impairment vs unchanged or improved) and age, sex and maximum impairment grade at diagnosis in 706 MB patients registered in field clinics in the Western Region, Nepal.*

Variable	Adjusted OR ^a	95% CI ^b	p Value
Age			
0–19*	1.0		
20–39	0.97	0.40–2.36	0.95
40–59	1.55	0.65–3.70	0.32
≥ 60	1.82	0.66–4.98	0.25
Sex			
Males	1.03	0.62–1.71	0.91
Females*	1.0		
Maximum impairment grade at diagnosis			
No impairment* (0)	1.0		
Sensory impairment (1)	1.87	1.06–3.32	0.031
Visible deformity (2)	1.98	1.15–3.40	0.014

^aOdds ratios (OR) derived from logistic regression examining the joint effect of age, sex, classification and impairment grade at diagnosis using the category marked with an asterisk as the baseline.

^b95% confidence interval.

spective and that the data collection was, therefore, less controlled than in a prospective study. Prospective studies on the incidence and evolution of impairment during and after MDT are overdue.

The cumulative incidence of new impairment among patients without impairment at diagnosis was 10% over a 2-year period in the current study. For patients with initial impairment this figure was 20.5%. Data for comparison are few. Smith reported a 16.5% incidence of new nerve damage “during MDT” (16). We found a cumulative incidence of motor and/or sensory nerve impairment of 23.3% among 335 hospital outpatients over an average follow-up period of 21 months (21). More than half of these patients improved after steroid treatment, so the proportion of patients left with new impairments at the end of 2 years was comparable to the above figure of 10%. Among 118 patients with impairment followed over a 4-year period in India, 16.1% improved and 23.7% deteriorated (16). Pon-nighaus and Boerrigter prospectively followed a group of MB patients, randomized into taking either one of two fixed-duration MDT regimens, for an average of about 3 years (13). In the initially impairment-free group, 28/201 (13.9%) developed new impairment during the study period, while 52/104 (50%) with a pre-existing impairment deteriorated. This gives a risk ratio among these patients of 3.6 (95% CI 2.42–

5.32), suggesting a 3.5-times increased risk of developing impairment among those already impaired at diagnosis. Among our study patients, the presence or absence of impairment at diagnosis also proved to be the major risk factor for developing new impairment. When the effects of age, sex, classification and impairment grade at diagnosis were examined in a joint model, only the effect of the latter remained as an independent risk factor (Table 6; OR 1.98, 95% CI 1.15–3.4).

It is important to note that the near-twofold increase in risk was almost equal in patients who “only” had sensory impairment at diagnosis to those who already had visible deformity. This emphasizes the importance of detecting sensory impairment and taking appropriate measures to prevent secondary tissue damage. It also highlights the importance of reporting patients with sensory impairment in routine statistics used for monitoring, evaluation and planning. The only impairment-related indicator commonly used in routine statistics is the “proportion of patients with WHO grade 2 among new cases.” While this may be a useful indicator of delay in case finding, it completely overlooks a very substantial group of patients at risk. We would strongly recommend that influential bodies such as WHO and ILEP would require reporting of the proportion of patients with grade 1 and the proportion with grade 2 at diagnosis and at RFT.

Radhakrishna and Nair reported data that yielded an incidence rate of deformity of approximately 71.5/1000 patients per year among borderline, indeterminate and lepromatous patients (¹⁴). This would give a cumulative incidence of 14% over 2 years. These data did not include sensory impairment as "deformity." However, the overall incidence is in the same order of magnitude as in the above-mentioned studies. Using a stratified analysis, Radhakrishna and Nair showed an association between the incidence of deformity and age, sex, type of leprosy and treatment (dapsone) regularity. Patients who were more regular in attending for treatment were more likely to develop deformity. Several other authors have also reported this apparent association (^{6, 19}). Others have pointed out that this association may be due to confounding (^{5, 8}). Patients with (more severe) impairment or who develop impairment are likely to be more motivated to attend for treatment than those with minor or no impairment.

A much lower incidence of only 0.6% "disability" was reported by Keeler and Ryan among 335 patients without impairment at diagnosis during a 2- to 6-year follow-up period. The reason for this low incidence is not clear. Ponnighaus, *et al.* report an equally low incidence rate of "disabilities" of 2.9/1000 person years at risk during MDT among 1229 patients in Malawi. However, most of these patients were PB (tuberculoid), who have a much lower incidence of impairment (¹⁴). The incidence of impairment among MB patients from the same area, described by Ponnighaus and Boerrigter, was comparable to ours (see above).

Conclusions. 1. In a cohort of 1082 MB patients in the Western Region of Nepal, the majority had some impairment at diagnosis (55.8%). 2. After 2 years, the proportion impaired had decreased to 43.9%, a net improvement of 12%. 3. Among patients without impairment at diagnosis, 10% had developed some after 2 years. The risk of developing impairment was almost double for those with sensory impairment and those with visible deformity at diagnosis. 4. For purposes of monitoring, evaluation and planning, both the proportion of patients with sensory impairment (WHO grade 1) and the proportion with visible de-

formity (WHO grade 2) should be reported at diagnosis and at RFT.

SUMMARY

Study aim: To investigate the progress of impairment over time in multibacillary (MB) leprosy patients.

Study design: Retrospective cohort study.

Study population: One-thousand-eighty-two MB patients newly registered in nine field clinics in the Western Region of Nepal between 1980 and 1993.

Methods: Data on impairment at diagnosis and at yearly intervals afterward were collected from patient records of MB patients already released from multidrug therapy (MDT). The World Health Organization (WHO) 1988 "disability" grading scale (0–2, for both eyes, hands and feet—six sites) was used as a measure of impairment. For the analysis we summed the WHO grading for the six sites into an eyes-hands-feet (EHF) sum score (minimum 0, maximum 12). The EHF score at 2 years of follow up was used to compute the main outcome measures: impairment at 2 years, yes or no, and deterioration of impairment compared with diagnosis. The combined effect of age, sex, classification and impairment status at diagnosis on the outcome was examined with logistic regression.

Results: At diagnosis, 55.8% of the patients had some impairment. This proportion decreased over 2 years to 43.9%. Among patients without initial impairment, 31/310 (10%) developed impairment during the study period. This was 81/396 (20.5%) among patients with impairment at diagnosis. The adjusted odds ratio (OR) for developing impairment was 1.87 [95% confidence interval (CI) 1.06–3.32] for patients with initial sensory impairment (WHO grade 1) and 1.98 (95% CI 1.15–3.4) for those with initial visible deformity (WHO grade 2). Among patients with impairment at diagnosis, 195/396 (49.2%) had improved after 2 years.

Conclusions: The proportion of patients with impairment after 2 years of antileprosy treatment was 12% less than at diagnosis. Among patients without initial impairment, 10% had developed some impairment after 2 years. The risk of developing impairment was almost double for those with sensory impairment or visible deformity at diagno-

térations visibles devraient toutes deux être rapportées au moment du diagnostic et à la fin du traitement.

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