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Field treatment of acute nerve function impairment in leprosy using a standardized corticosteroid regimen—first year's experience with 100 patients

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Summary In this study, a fixed regimen of prednisolone for the treatment of acute nerve function impairment (NFI) in leprosy patients was developed and introduced at field level in one area (Thakurgaon) of the Danish–Bangladesh Leprosy Mission's field in NW Bangladesh. The assessment, management and follow-up of patients was undertaken by leprosy control supervisors and physiotechnicians.

One hundred patients were treated and followed up 6–8 months after completion of a 4-month course of prednisolone. At a level of change of 2 points (where a change of at least 2 points in the motor/sensory score was taken to indicate a change of status, i.e. full or partial recovery, or deterioration), 42/65 (64·6%) patients with sensory loss experienced some sensory recovery at completion of prednisolone treatment, and 40/65 (61·5%) at 6–8 months' follow-up. 41/85 (48·3%) of patients with motor loss experienced improvement, and 42/85 (49·4%) at follow-up. Analysis of the mean scores at start of prednisolone treatment, completion and at follow-up using Student's *t*-test showed highly significant ($p < 0{\cdot}001$) differences between scores before and after treatment. The benefit is maintained as seen after a period of 6–8 months follow-up.

It was concluded that treatment of acute nerve function impairment at field level by paramedical workers, using a standardized regimen of prednisolone is feasible, practical and effective.

Introduction

In many leprosy control programmes, treatment of leprosy reactions using corticosteroids

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is confined to a hospital setting. Unfortunately, a proportion of patients who would benefit from corticosteroid administration are for various reasons unable or unwilling to be admitted to hospital. As a result they go on to develop nerve function impairment (NFI) with resulting disability and handicap. This problem was phrased by Becx-Bleumink *et al.* as follows: *'When the management of patients on corticosteroids is the responsibility of medical officers only, we will deprive many patients of adequate treatment for their reactions.'* [1] A recent study of a cohort of new patients in Bangladesh that started MDT in 1990 shows that over a third of cases with recent NFI were not treated with corticosteroids for the above reason.[2] Introduction of treatment in the field of recent NFI using standardized corticosteroid regimens has been hesitant. Organizational and logistic problems are one reason, reservations concerning side-effects of corticosteroids, and placing the responsibility of their management into the hands of paramedical workers, another.

It is well known that corticosteroids are effective in the treatment of leprosy reactions and acute NFI in leprosy.[1,3–7] It is generally agreed that in order to be effective, corticosteroids must be administered within 6 months of an episode of NFI.[1,8] As stated above, attention has been drawn to the need for such treatment to be given by suitably trained field workers in order for the maximum number of patients to receive benefit.[1,9]

Several standardized or semi-standardized regimens for the treatment of NFI have been proposed using prednisolone. For example, 40 mg/day tapering over 12 weeks for paucibacillary (PB) patients and 20 weeks for multibacillary (MB) patients.[9] Another regimen recommended is 25 mg prednisolone daily, reducing by 5 mg per month.[6] For the latter regimen it was recommended that the starting dose should be higher for 'severe reactions'.

All of the studies referred to above comment on the absence of serious side-effects of prednisolone in relatively long courses. A recent meta-analysis reviewing 93 articles and 6602 patients found that peptic ulceration was not significantly associated with prolonged steroid use.[10] In the meta-analysis, a mean daily dose of 35-mg prednisolone for a mean duration of 64 days was given—comparable to the courses used for the treatment of leprosy reactions.[11] Other side-effects including diabetes, hypertension, psychosis and dermatological side-effects were found to be significantly associated, but bacterial sepsis, osteoporosis and tuberculosis while occurring more frequently in the treatment group, did not achieve statistical significance. Overall, a picture of relative *safety* emerged from this meta-analysis.

In 1994 the Danish–Bangladesh Leprosy Mission (DBLM) began with the implementation of a fully field-based programme of the treatment of leprosy reactions and acute NFI. The decision to give corticosteroids to individual patients was delegated to the lowest appropriate level, that of leprosy control supervisor (LCS) and physiotechnician (PT). A protocol for management of reactions was developed by a committee, training provided, and a 7-month pilot programme initiated. This study reports on the outcome of this initial programme after the first year's experience.

Methods

LOCATION

The study was conducted at the Danish–Bangladesh Leprosy Mission (DBLM) in

Nilphamari, in NW Bangladesh. DBLM is a private organization involved in a vertical leprosy programme situated in a highly endemic area (prevalence: 5/1000).[12] The field programme is geographically divided into three 'fields', each with separate reporting. One area, the Thakargaon field, was selected for this study. It covers the two districts of Thakargaon and Panchagar with a total area of 3,214 km^2 and 1,7 million population (1991 census).

ORGANIZATIONAL STRUCTURE

The DBLM Thakargaon field is divided into 6 'blocks', each with its own staffing of leprosy control assistants (LCA) who work under the direction of a leprosy control supervisor (LCS), responsible for that block. In turn, the LCS relates to the leprosy control officer (LCO) who is responsible for the entire field. The LCO relates directly to the field director, who is a medical officer. In addition, there are physiotechnicians (PT) assigned to the field who visit on every clinic day and who are involved in nerve function testing, the teaching of special exercises and health education. New leprosy cases are charted by LCAs who also take skin smears. The cases are then confirmed by the LCS, and MDT is given at his direction. All cases at every clinic visit (during multidrug therapy (MDT) and surveillance) have sensory testing and quick muscle testing carried out by the LCA. If any abnormality is found, the case is referred to the PT and LCS for confirmation. Equivocal results were not accepted for corticosteroid treatment and in such cases were reassessed the following month.

NERVE FUNCTION TESTING

Sensory testing was carried out using a ball-point pen as described by Watson.[13] Testing took place at 12 standard points on each hand palm and 11 standard points on each foot sole. Either partial or complete anaesthesia was taken as a positive finding. The sensory score is calculated by counting the number of sensory points which were abnormal. **Motor function testing** of the facial, radial, ulnar, median and lateral popliteal nerves was carried out by means of 'quick muscle testing' (QMT) and graded according to a revised MRC scale[14] (Table 1). The regular MRC score was *reversed* so that zero always indicated normality for both motor or sensory testing. The reversed score is referred to as the *DBLM score*. Details of muscles tested are also given in Table 1. Each muscle or muscle group tested is assigned a DBLM score up to a maximum of 5.

Corneal sensation testing was performed in those patients who were observed to blink infrequently (less than 5 times per minute), but the evaluation of this parameter is not included in this study.

ACUTE NFI TREATMENT PROTOCOL

The complete guidelines as used for this study are reproduced in the Appendix. According to these guidelines leprosy reactions and NFI are graded according to severity and treatment assigned accordingly. Patients with signs of acute NFI were given 40-mg prednisolone daily and tapered off over 4 months in the field. This was

Table 1. Muscle strength scoring (MRC scale[14])

Muscle strength finding	MRC score	DBLM score
Full ROM[1], full resistance	5	0
Full ROM, reduced resistance	4	1
Full ROM, no resistance	3	2
Reduced ROM, some joint movement	2	3
Flicker only	1	4
Full paralysis	0	5

[1]ROM = range of movement.
Details of muscles tested in quick muscle test:

Facial nerve:	Tight eye closure (orbicularis oculi)—MRC scale
	Lid gap on light eye closure (mm)
Ulnar nerve:	Abduction of little finger
Median nerve:	Abduction of thumb
Radial nerve:	Wrist extension
Lateral popliteal nerve:	Dorsiflexion of foot; Eversion of foot

defined as the reduction by 1 point in the MRC muscle strength grade of any of the movements routinely tested in the QMT; the loss of 1 standard sensory point on the hands or feet; or the development of corneal anaesthesia. Acute was taken to mean occurring within the previous 6 months. Other signs of leprosy reaction or NFI may or may not have been present, e.g. inflamed skin patches, painful nerves.

Patients with acute NFI according to the criteria of DBLM grade 2 (see Appendix) seen between July 1994 and January 1995 were included in this study. There were no patients with impairments according to DBLM grade 3, although patients whose nerve function deteriorated after starting field prednisolone were admitted during treatment. Patients with signs of Type I reaction or neuritis without signs of NFI (DBLM grades 1a and 1b) were excluded, even if they were treated with prednisolone. Out of the initial group of 103, one died and two were lost to follow-up. A total of 100 patients were included in the study group.

Table 2. General data of 100 patients who received a standardized regimen of prednisolone in the field

Age in years at diagnosis acute NFI	Male		Female		Both sexes			Status		
	PB	MB	PB	MB	PB	MB	Tot	New pt	On MDT	RFT pt
0–9	0	0	0	1	0	1	1	1	0	0
10–19	3	5	1	4	4	9	13	3	8	2
20–29	3	10	3	2	6	12	18	4	8	6
30–39	4	16	4	7	8	23	31	9	15	7
40–49	1	8	1	7	2	15	17	2	11	4
50–59	2	6	2	4	4	10	14	8	3	3
>60	2	3	0	1	2	4	6	2	3	1
Total	15	48	11	26	26	74	100	29	48	23

FOLLOW-UP

Data relating to NFI was collected at the followings times:

0 Before the start of the acute NFI episode (usually at registration).
I At the start of field prednisolone treatment.
II At completion of field prednisolone treatment.
III 6 to 8 months after completion of field prednisolone treatment.

(The measurement of NFI scores before starting field prednisolone treatment was not possible in new patients presenting in reaction or with acute NFI.)

DEFINITIONS OF OUTCOME

Full recovery — Restoration of sensory or motor score to zero (normality).
Partial recovery — Partial improvement in sensory or motor score.
Same — No overall change in sensory or motor score.
Deterioration — Deterioration in sensory or motor score.

Results

Table 2 shows the general data of the 100 patients who received a standardized regimen of prednisolone in the field. The mean age of patients was 35·3 years (median: 34·5 years, range: 8–70 years). The distribution of study patients according to the Ridley–Jopling classification was as follows: BT: 64; BB: 12; BL: 13; LL: 7; PN: 4.

The outcome of sensory function amongst the study group is shown in Table 3, the outcome of motor function is shown in Table 4. Outcome has been expressed at different 'sensitivity levels'. Where a change of ≥ 1 point in the sensory score was taken as

Table 3. Outcome of sensory function amongst study group patients with acute sensory loss expressed at three levels of sensitivity ($n = 65$)

	At end of prednisolone therapy						6–8 months after completion of prednisolone therapy					
	Outcome at 3 sensitivity levels* (absolute)			Outcome at 3 sensitivity levels* (%)			Outcome at 3 sensitivity levels* (absolute)			Outcome at 3 sensitivity levels* (%)		
Outcome	≥1	≥2	≥3	≥1	≥2	≥3	≥1	≥2	≥3	*≥1*	*≥2*	*≥3*
Full	25	19	16	*38·5*	*29·2*	*24·6*	25	19	15	*38·5*	*29·2*	*23·1*
Partial	28	23	16	*43·1*	*35·4*	*24·6*	25	21	18	*38·5*	*32·3*	*27·7*
Same	6	21	31	*9·2*	*32·3*	*47·7*	4	18	27	*6·1*	*27·7*	*41·5*
Deteriorated	6	2	2	*9·2*	*3·1*	*3·1*	11	7	5	*16·9*	*10·8*	*7·7*
Total	65	65	65	*100*	*100*	*100*	65	65	65	*100*	*100*	*100*

***Sensitivity levels** Outcome is expressed at 3 sensitivity levels. These indicate numbers of patients whose sensory scores changed either ≥1, ≥2 or ≥3 points relative to the score at start of prednisolone therapy.

Table 4. Outcome of motor function amongst study group patients with acute motor loss expressed at three levels of sensitivity ($n = 85$)

	At end of prednisolone therapy						6-8 months after completion of prednisolone therapy					
	Outcome at 3 sensitivity levels* (absolute)			Outcome at 3 sensitivity levels* (%)			Outcome at 3 sensitivity levels* (absolute)			Outcome at 3 sensitivity levels* (%)		
Outcome	≥1	≥2	≥3	*≥1*	*≥2*	*≥3*	≥1	≥2	≥3	*≥1*	*≥2*	*≥3*
Full	52	27	14	*61·2*	*31·8*	*16·5*	60	34	18	*70·6*	*40·0*	*21·2*
Partial	27	14	8	*31·8*	*16·5*	*9·4*	17	8	6	*20·0*	*9·4*	*7·1*
Same	4	42	63	*4·7*	*49·4*	*74·1*	3	39	58	*3·5*	*45·9*	*68·2*
Deteriorated	2	2	0	*2·4*	*2·4*	*0*	5	4	3	*5·9*	*4·7*	*3·5*
Total	85	85	85	*100*	*100*	*100*	85	85	85	*100*	*100*	*100*

***Sensitivity levels** Outcome is expressed at 3 sensitivity levels. These indicate numbers of patients whose motor scores changed either ≥1, ≥2 or ≥3 points relative to the score at start of prednisolone therapy.

significant, a total of 81·6% of patients showed sensory improvement after completion of prednisolone therapy (38·5% with full recovery), a percentage maintained with 77% improved (38·5% full) after 6–8 months of follow-up. With a change of ≥ 2 points in the sensory score, this was 64·6 % (29·2% full) at completion of therapy and 61·5% (29·2% full) at 6–8 months; at the ≥ 3-point change in sensory score there was 49·2% (24·6% full) at end of therapy and 50·8% (23·1% full) at follow-up. Thus, the level of improvement in sensory function was of the order of 50–60% at more conservative levels of sensitivity, a level which was maintained 6–8 months after the end of

Table 5. Total sensory scores and mean sensory scores at diagnosis of NFI (I), completion of prednisolone therapy (II), and at follow-up (III), with significance of mean differences calculated using *t*-test. Complete anaesthesia of hands and feet in one patient would score 46, with a best possible total score of 0

		Total sensory scores			Mean sensory scores			*p*-value of mean differences		
Category	*n*	I	II	III	I	II	III	I–II	I–III	II–III
Male	37	401	187	227	10·84	5·05	6·14	<·001	<·001	·347
Female	28	228	122	133	8·14	4·36	4·75	·001	·042	·778
PB	14	149	81	71	10·64	5·79	5·07	·024	·016	·325
MB	51	480	228	289	9·41	4·47	5·67	<·001	·002	·278
<1 month*	28	300	180	133	10·71	6·43	4·75	<·001	<·001	·109
1–3 months*	26	267	77	164	10·27	2·96	7·31	<·001	·024	·058
4–6 months*	11	62	52	63	5·64	4·73	5·73	·453	·957	·484
All	65	629	309	360	9·68	4·75	5·54	<·001	<·001	·372

*Duration of NFI.

prednisolone treatment. Comparison of mean differences in sensory scores calculated before and after prednisolone therapy (Table 5) shows highly significant differences for mean scores both immediately after prednisolone and at 6–8 months' follow-up using the Student *t*-test ($p < 0{\cdot}001$). The only exception was for the small group of patients with NFI of 4–6 months' duration ($n = 11$) where there was no significant differences between the mean scores before treatment and at either time after treatment. Although this number is too small to draw statistical conclusions from, it suggests that there may be less recovery in patients with more established NFI. There was no significant difference between mean sensory scores immediately after prednisolone treatment and at 6–8 months' follow-up ($p = 0{\cdot}372$), indicating that sensory recovery is maintained.

Turning to motor recovery, there is also a good level of response, but less marked than for sensory outcome. At the $\geq$1 point change of motor function score there is a 93% (61·2% full) overall improvement at the end of prednisolone therapy and 90·6% (70·6% full) at end of follow-up. However, at the $\geq$ 2-point level it is 48·3% (31·8% full) and 49·4% (40% full) respectively. At the $\geq$ 3 level it is 25·9% (16·5% full) and 28·3% (7·1% full) respectively. Thus the level of motor recovery was in the range 25–50% at the $\geq$2 or $\geq$3 point levels in change of motor function score. Again, analysis of mean differences using the Student *t*-test between mean motor scores before and after prednisolone treatment showed a highly significant difference with $p < {\cdot}001$. Interestingly, the longer duration NFI group (4–6 months' duration) did show a significant difference in mean scores before and after treatment ($p = 0{\cdot}001$), unlike the parallel sensory group. Again, there was no significant difference between mean motor scores immediately after prednisolone treatment and at 6–8 months' follow-up ($p = 0{\cdot}361$), indicating that motor recovery, like sensory recovery, is maintained.

Discussion

This study is primarily concerned with the feasibility and effectiveness of treating acute NFI with a standardized regimen of prednisolone in the field. A single standardized regimen for the treatment of NFI was developed based on the recommendations made by Rose & Waters[9] as well as Becx-Bleumink.[1] This was taught to field staff in the DBLM Thakurgaon field and implemented, using experienced leprosy control supervisors and physiotechnicians as the key persons at field level to assess patients and give treatment.

Results of the field treatment of NFI with prednisolone were analysed in two separate ways: the first method described change in nerve function in terms of full and partial recovery, same (no change) and deterioration, using three different levels of sensitivity in defining a relevant change in sensory or motor function score. In the second method mean differences of total sensory and motor function scores at the time of diagnosis, completion of prednisolone therapy and after follow-up were compared and statistically analysed. Both approaches demonstrate marked improvement in both sensory and motor function, even when applying the very strict criteria of a change of $\geq$3 points in the sensory and motor function scores. This conclusion applies to the overall study group. Only in patients with NFI of 4 to 6 months duration, improvement in the sensory scores in marginal, if at all (Table 5). There does seem to be

Table 6. Total motor scores and mean motor scores at diagnosis of NFI (I), completion of prednisolone therapy (II), and at follow-up (III), with significance of mean differences calculated using *t*-test. Complete motor paralysis of hands and feet in one patient would score 25, with a best possible total score of 0

		Total motor scores			Mean motor scores			*p*-value of mean differences		
Category	*n*	I	II	III	I	II	III	I–II	I–III	II–III
Male	56	171	64	72	3·05	1·14	1·29	<·001	<·001	·453
Female	29	71	22	28	2·45	0·76	0·97	<·001	·001	·607
PB	20	48	12	13	2·40	0·60	0·65	<·001	<·001	·834
MB	65	194	74	87	2·98	1·14	1·34	<·001	<·001	·375
<1 month*	34	94	36	48	2·76	1·06	1·41	<·001	·002	·321
1–3 months*	37	107	36	34	2·89	0·97	0·92	<·001	<·001	·827
4–6 months*	14	41	14	18	2·93	1·00	1·29	<·001	<·001	·218
All	85	242	86	100	2·85	1·01	1·18	<·001	<·001	·361

*Duration of NFI.

improvement in the motor scores in this group (Table 6). The size of the study was too small to identify risk factors for nerve damage and to look at the response of subsets of patients to treatment. However, that is the subject of a large prospective cohort study into acute nerve damage now running in DBLM (Bangladesh acute nerve damage study).

The results of this study compare well with those of Van Brakel & Khawas.[7] In that study touch sensibility testing was performed using a nylon monofilaments giving a force of 10 g for the hands, and a thicker one giving a force of 75 g for the sole of the foot, whereas DBLM uses the ball-point pen in the field. The criteria they used for change in sensory and motor function are a difference of more than 1 point (or ≥ 2) on the touch sensibility test (TST) or voluntary muscle test (VMT). Van Brakel & Khawas analyse in depth changes seen in individual nerves and also describe time trends and prognostic factors, elements outside the scope of the study presented in this paper. Nevertheless, the overall picture of improvement in sensory scores (app. 65%), and motor function scores (app. 50%) at a change of ≥ 2 point in score, is similar. The improvement was maintained over a follow-up period of more than 6 months.

A number of patients experienced deterioration in nerve function during the period, including a few patients who initially fully recovered. All of these patients required a second course of prednisolone or a hospital admission. However, given that a fixed regimen was used (the field staff were not given freedom to alter it at will) the results can still be considered as very satisfactory.

In this study, no cases of peptic ulcer, TB, sepsis or psychosis occurred. Blood pressure was not routinely measured by field staff and urine glucose was also not tested. Dermatological side-effects including acne, tinea corporis and cushingoid fat redistribution occurred only in a small number of patients. The overall experience has been very positive with the field staff enthusiastic towards the programme despite the increased workload for them. They reported good compliance from patients once they understood that they were avoiding a hospital admission; positive feedback from patients recovering lost nerve

function; and the staff themselves felt happy about their increased responsibility. Since the field treatment of reactions has been extended to the whole of DBLM there has been a marked drop in hospital admissions, freeing beds which are now being used for an increasingly busy reconstructive surgery programme.

We share the conclusion of Van Brakel & Khawas[7] that further research is needed to optimize the results of treatment of acute NFI. There are still too many patients for whom the present detection and treatment options are not sufficient, and who remain with impairments after successful treatment of their leprosy infection with MDT. On the other hand we are strongly convinced that as a first step, and pending further improvements in detection and therapy, the present knowledge and possibilities of early detection and treatment of NFI should be made available for *all* leprosy patients. This study shows that field treatment of NFI with a standardized regimen of prednisolone, administered by paramedical staff is feasible, practical and effective.

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Appendix

Table showing treatment regimens for Type I reactions/neuritis

Grade/symptoms	Action
DBLM Grade 1a • Reacting skin patch not overlying truncal nerve • Mild nerve pain only • No sensory or motor loss	• **Aspirin** for up to 3 weeks (or PARACETAMOL if problems) • ST/QMT by LCA • Weekly follow-up and medicine supply • *If no improvement, grade as DBLM 1b*
DBLM Grade 1b • Reacting skin patch not responding to Aspirin • Reacting skin patch overlying truncal nerve or any big facial patch • Cutaneous neuritis • No sensory or motor loss	• **Low dose prednisolone** (not reproduced here) • ST/QMT by LCA • Body chart if RFT • Skin smear if RFT • Weekly follow-up 1 month, then 2 weekly • *If no improvement, grade as DBLM grade 2*
DBLM Grade 2 • Grade 1b pt not responding to low-dose Prednisolone • New sensory loss • New motor loss to not less than MRC grade 3 • Moderate/severe painful nerve trunk • Ulcerating/extensive skin reaction • Not pregnant/no ulcer present • Eye not in danger[1] • *Sensory/motor score must have newly decreased by at least 1 point*	• **Full-dose type 1 prednisolone** (see dose regimen) • ST/VMT by physiotechnician • Body chart if skin reaction present • Skin smear if RFT • Record level of pain[2] • Fill up reaction treatment record sheet • Rest, splinting, warmth, exercises as appropriate by PT/LCS • Weekly review at home 1 month, then 2 weekly • ST/VMT by PT at clinic on visits 1,2,last (at least) • *If patient worsens, grade as DBLM grade 3*
DBLM Grade 3 • Grade 2 patient not responding to full-dose prednisolone • New motor loss to less than MRC grade 3 • Eye in danger[1] • Pregnant patient/patient with ulcer with reaction needing steroids • Any seriously ill patient • Patient with compelling social reasons	• **Admit to hospital** • Patients refusing to go to hospital can be treated in the field using full-dose prednisolone except if pregnant

[1]**Eye in danger:** New development of lid gap, loss of blinking reflex or corneal anaesthesia.
[2]**Pain level:** Severe—disturbs sleep; Moderate—sleep OK, painful at work; Mild—slight problem; Tender - painful on pressure only.

Dosage of prednisolone used in treatment of acute nerve damage ('Full dose prednisolone')

Adult > 35 kg		Small adult child 10–14 y 20–35 kg		Child 6–9 y 15–19 kg		Child < 6 y < 15 kg	
40 mg/d	4 wks	30 mg/d	4 wks	20 mg/d	4 wks	10 mg/d	4 wks
30 mg/d	2 wks	25 mg/d	2 wks	15 mg/d	2 wks	5 mg/d	4 wks
25 mg/d	2 wks	20 mg/d	2 wks	10 mg/d	2 wks	2·5 mg/d	2 wks
20 mg/d	2 wks	15 mg/d	2 wks	5 mg/d	2 wks		
15 mg/d	2 wks	10 mg/d	2 wks				
10 mg/d	2 wks	5 mg/d	2 wks				
5 mg/d	2 wks						
Total	**16 wks**	**Total**	**14 wks**	**Total**	**10 wks**	**Total**	**10 wks**