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Letter to the Editor

A SCALE TO ASSESS THE SEVERITY OF LEPROSY REACTIONS

Recognising and assessing the clinical signs and severity of leprosy reactions is essential for diagnosis and treatment. To promote such awareness there is a potential role for a severity scale that would draw attention to the early signs of leprosy reactions, the choice of treatment and to changes in response to treatment. Early work by Naafs & van Droogenbroeck produced a composite measure called the '*indice névritique'* (neural index), which used various measures, including motor nerve conduction, an early type of monofilament sensory testing, voluntary muscle testing and nerve enlargement.[1,2] Despite them demonstrating the utility of this measure, it was not used, possibly because it included neurophysiological measures, which are frequently not available in centres managing leprosy patients. Unpublished work by Alison Anderson and others at Green Pastures Hospital & Rehabilitation Centre in Pokhara, Nepal, explored the potential of another scale to measure reaction severity. The use of a scale has been reported elsewhere in Nepal.[3]

Methods

As part of the ILEP Nerve Function Impairment and Reaction (INFIR) Cohort Study,[4] we monitored clinical status and changes in nerve function in advance of Type 1 or Type 2 reactions and undertook a pilot exercise that assessed 21 items as the basis for a reaction severity scale. These included assessment of skin signs, fever, oedema and forms of neuritis plus changes in sensory and motor function assessed using monofilaments (200 mg, 2 g, 4 g, 10 g and 300 g) and voluntary muscle testing (VMT) respectively. Monofilament assessments at each test point were scored 0 where the 200 mg monofilament was felt through to 5 where the 300 g monofilament was not felt. Muscle testing was scored using the standard Medical Research Council (MRC) grading, normal (5), full range of movement but reduced resistance (4), full range of movement but no resistance (3), movement but reduced range (2), muscle flicker (1) and paralysed (0).[5] For the eye, any gap on strong closure was substituted for movement but reduced range. Figure 1 summarises test points for hands and feet and the method of calculation of a severity score ranging from 0 to 70, higher scores being associated with more severe reactions.

Originally, the scoring of the items in the 'A-section' of the severity scale was weighted in such a way that a score of '3' or more on any individual item would trigger the diagnosis that the outcome event (reaction or nerve function impairment) was severe and required (steroid) treatment. In the 'B-section' a score of '2' or more triggered the diagnosis 'severe'.

We used assessments of reaction status at intake from all the 303 cases recruited to the INFIR Cohort Study to assess scale reliability. Since there were just five individuals diagnosed with Type 2 reactions the focus here is primarily on Type 1 reactions and recent change in sensory or motor function. Cronbach's alpha was used as a measure of internal reliability or consistency of the composite severity score.[6] The value of alpha ranges between 0–1. A value close to 1 indicates high internal agreement of the different components, i.e., they fit well together. We used Principal Component Analysis (PCA) to examine clusters of items within the scale that appear to belong together (factors).[7] Each factor explains part of the variability of scores obtained with the scale. Particular sub-scales may be identified in this

Reaction Severity Assessment

Section A· Score reaction signs and symptoms in the right hand column:

	Scoring:	0	1	2	3	4	Score
A1	Number of raised and inflamed lesions	None	1–3	4–10	>10		
A2	Degree of inflammation of skin lesions or nodules	None	Erythema or nodules	Erythema, raised Plaques or nodules	Ulceration		
A3	Peripheral oedema due to reaction	None	Minimal	Visible, but not affecting function	Oedema affecting function		
A4	Fever due to reaction	<37·5	37·6–38·9		≥39		
A5	Involvement of other organs (eye, testes etc)	None			Mild	Definite	
A6	Nerve pain and/or paraesthesia	None	Intermittently, not limiting activity		Sleep disturbed and/or activity diminished	Incapacitating	
A7	Nerve tenderness on gentle palpation	None	Absent if attention is distracted		Present if attention is distracted	Withdraws limb forcibly	

Section B· Score sensory assessments in the right hand column:

	Scoring:	0	1	2	3	Score
B1	Ulnar – left	No recent worsening	1 to 2 points worse	3 to 8 points worse	9 to 16 points worse	
B2	Ulnar – right	No recent worsening	1 to 2 points worse	3 to 8 points worse	9 to 16 points worse	
B3	Median – left	No recent worsening	1 to 2 points worse	3 to 8 points worse	9 to 16 points worse	
B4	Median – right	No recent worsening	1 to 2 points worse	3 to 8 points worse	9 to 16 points worse	
B5	Pos· Tib· left	No recent worsening	1 to 2 points worse	3 to 8 points worse	9 to 16 points worse	
B6	Pos· Tib right	No recent worsening	1 to 2 points worse	3 to 8 points worse	9 to 16 points worse	

Section C - Score motor assessments in the right hand column:

	Scoring:	0	1	2	3	Score
C1	Facial – left	No recent worsening	1 point worse	2 points worse	3 to 5 points worse	
C2	Facial – right	No recent worsening	1 point worse	2 points worse	3 to 5 points worse	
C3	Ulnar – left	No recent worsening	1 point worse	2 points worse	3 to 5 points worse	
C4	Ulnar – right	No recent worsening	1 point worse	2 points worse	3 to 5 points worse	
C5	Median – left	No recent worsening	1 point worse	2 points worse	3 to 5 points worse	
C6	Median – right	No recent worsening	1 point worse	2 points worse	3 to 5 points worse	
C7	Lat· Pop· – right	No recent worsening	1 point worse	2 points worse	3 to 5 points worse	
C8	Lat· Pop· – left	No recent worsening	1 point worse	2 points worse	3 to 5 points worse	

Total score, sections A + B + C:	

Figure 1. Severity Scale coding and data collection.

way (principal components). Analysis of variance was used to compare severity score means between groups. Formal validation of a scale requires that scores be compared with an independent clinical assessment of severity. Since the INFIR Cohort Study entailed some 3 hours of neurological and other assessments at each follow-up visit we were unable to complete this additional assessment. However, an independent but retrospective assessment of clinical records identified 85 individuals with severe reactions, 30 with moderate reactions and 43 with mild reactions at intake.

Results

Our analysis gave a value for Cronbach's alpha of 0.77, indicating good agreement between items. PCA identified a main factor accounting for 45% of total variance and a second factor explaining an additional 26% of the variation. Figure 2 compares the severity scores between the 'severity groups' identified by assessment of clinical records.

The mean severity score for individuals with no reaction was 0.88 (standard deviation 1.18), mild reactions 0.86 (sd 1.14), moderate reactions 4.1 (sd 2.90) and severe reactions 8.5 (sd 4.91). We found statistically significant differences in severity scores between groups but failed to differentiate between the groups with mild and no reaction.

Discussion

Our findings suggest that, subject to formal validation and reliability testing, a reaction severity score may play an important role in informing clinical decisions about reactions, the choice of treatment and monitoring progress. However, our findings raise issues concerning the choice and scoring of scale items and the relative importance of symptoms.

First, are there additional items or alternative forms of scoring that would make the scale more sensitive to differences in severity, specifically in relation to mild forms of reaction? Or does the current scale reflect reality, namely that there is not enough difference between a state of 'no reaction' and a 'mild reaction' to be worth detecting with a severity scale? Conversely, is there duplication in the listed items that produces a bias towards severe reactions? Further analysis of our data failed to identify such items or weightings.

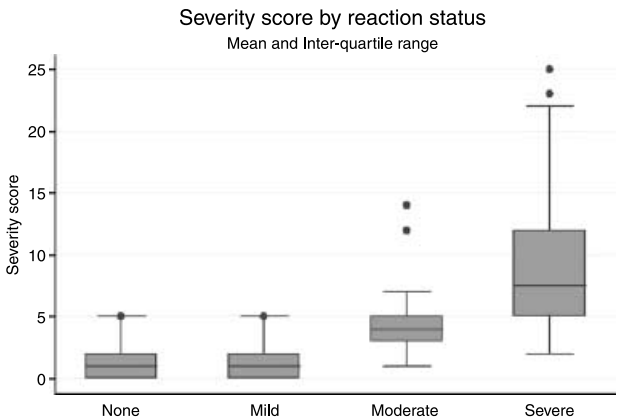

Figure 2. Mean, inter-quartile range, minimum and maximum of severity scores within groups independently assessed for reaction severity in the INFIR Cohort Study, Uttar Pradesh, India ($n = 303$).

The second point focuses on the relative importance of symptoms. While a value of 0.77 for Cronbach's alpha suggests good agreement between items, we noted that principal components analysis identified an additional independent factor (dimension) in the data that contrasted items describing skin signs with those describing sensory and motor function. This dimension accounted for 26% of the total variation and suggests that, while the combined items provide an adequate general measure of severity, there is a distinction between signs related to nerve function and other signs of reaction. This may be important in the light of the fact that some reactions manifest with skin and nerve involvement, while other reactions show only skin or only nerve involvement. Our coding system gave approximately equal weight to skin involvement and recent changes in nerve function. Does this reflect the relative clinical importance of these two groups of items? Given the longer-term implications of nerve impairment, is there a case for giving additional weight to items reflecting recent change in nerve function? Would this make the scale less sensitive to visible symptoms of reaction that may be the primary concern of the affected person?

We invite correspondence on these issues. Further (field)work on a severity scale for Type 1 reactions has started in 2006. There is also a separate research programme concerned with assessing the severity of Type 2 reactions.

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