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The concurrent validity of the Amharic version of Screening of Activity Limitation and Safety Awareness (SALSA) in persons affected by leprosy

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Summary

Objectives: Leprosy is endemic in many countries and results in activity limitations. There is a need for assessment tools to guide professionals in their evaluation and choice of intervention in order to improve conditions for leprosy-affected people. The purpose of our study was to evaluate the concurrent validity of the Amharic version of Screening of Activity Limitation and Safety Awareness (SALSA-am) scale with Amharic version of Disability of the Arm, Shoulder and Hand (DASH-am) questionnaire.

Design: Thirty-eight individuals with nerve damage due to leprosy completed the SALSA-am and DASH-am questionnaires. Spearman's rank correlation was used to determine relationships between SALSA and DASH scores. Specificity, sensitivity and accuracy were calculated.

Results: There was a good correlation 0·87 ($P < 0·001$) between SALSA-am and DASH-am scores. Sensitivity, specificity and accuracy were calculated with acceptable results.

Conclusions: SALSA-am is considered a useful questionnaire for determining activity limitations in persons affected by leprosy, and showed good correlation with DASH-am. The concurrent validity was considered good.

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Introduction

Leprosy neuropathy, if not treated early and adequately, may result in impairments, and in the longer term, activity limitations and participation restrictions. In the upper extremity, the most common impairments are due to either ulnar or combined ulnar and median nerve damage.[1,2] In the International Classification of Functioning, Disability and Health (ICF), disability is used as an umbrella term for impairments, activity limitations and participation. The ICF describes impairments as problems in body function or structure, and activity limitations as restrictions in individual activity performance. Participation restrictions are described as problems an individual may experience in different life situations.[3] In leprosy, impairments and activity limitations, as well as participation restrictions, are common.[1,2,4–9]

Impairments are often caused by peripheral neuropathy in the upper extremity. Typical primary impairments are loss of sensation, touch and temperature, dryness of the skin, muscle weakness or paralysis.[1,2,5,6] These impairments may result in loss of positioning and grip or pinch strength.[5] If treatment is not begun in time, nerve damage can be irreversible and primary impairments can lead to secondary impairments, e.g. skin cracks wounds, muscle atrophy, clawing of digits, contractures and absorption of fingers.[2,5–7]

Activity limitations are common when impairments make the activity difficult to perform. As many daily activities require grip or mobility of the hands, an impaired hand function and loss of sensibility can mean difficulties in self-care such as eating, dressing or writing, work related activities or leisure.[7,8,10] The risks for injuries due to the sensory loss are high in many activities, particularly when repetitive stress, excess pressure, burns or friction are included.[2,8]

In order to measure the impact of clinical interventions, validated measurement methods are needed.[11–13] In addition, there is a need for assessment tools that are easy to use in clinical practice. The Screening of Activity Limitation and Safety Awareness (SALSA) scale is a short questionnaire developed by the SALSA Collaborative Study Group in five leprosy endemic nations on three continents (Brazil, China, India, Israel and Nigeria). It is based on the ICF and provides a standardised measure of activity limitation in patients with peripheral neuropathy due to leprosy or diabetes. It is a 20 item questionnaire scoring activities such as mobility, self-care, work and dexterity. Fifteen questions are concerned with tasks completed using hands. The face and content validity of the original version of SALSA were considered good during the development of the questionnaire.[8] The content validity is dependent on the population and the settings where the questionnaire was developed.[12] To the best of our knowledge only a few studies have been published on validation of SALSA beyond the original English version.

The aspect of safety awareness provided by the SALSA scale is more relevant than other assessment tools due to them often lacking in sensibility and uniqueness specific to leprosy.[2] SALSA is quick and simple to use in clinical settings. No equipment is needed and no testing skills are required.[8]

A widely used global measurement method of assessing disabilities in the upper extremity is the Disability of the Arm, Shoulder and Hand questionnaire (DASH) that was developed by the American Association of Orthopedic Surgeons (AAOS) and the Institute for Work & Health in Canada. DASH is filled out by the patient and contains 30 questions on everyday activities that may be affected by a disorder of the hand and/or upper-extremity. The questions concern physical activities, symptom severity and the effect of the injury on social activities. DASH has been shown to have high validity and reliability in several diagnostic groups[12,14–23] and has previously been used as the gold standard.[24]

Compared to DASH, SALSA is shorter and includes a unique aspect of safety awareness. Validation of an Amharic version of SALSA would promote its use as a useful tool in the assessment of leprosy-affected people with peripheral neuropathy, and make assessment of disabilities in this context easier and faster.

The aim of this study was to evaluate the concurrent validity of the Amharic version of the Screening of Activity Limitation and Safety Awareness (SALSA-am) scale in people affected by leprosy, using the Disability of the Arm, Shoulder and Hand (DASH questionnaire) as the gold standard.

Methods

Data collection took place at the All Africa Leprosy, Tuberculosis and Rehabilitation Training (ALERT) Centre, Addis Ababa, Ethiopia[21] during two months in 2009. Included in the study were leprosy-affected people over 15 years of age with complete palsy of the ulnar or median nerve. Moderate secondary impairments such as contractures of less than 45 degrees, or mild absorption of one or more fingers were also accepted for inclusion. A convenience sample[18] was used, and all who met the inclusion criteria from in- or outpatients at the ALERT Centre, or nearby employment projects such as handicraft centres for those affected by leprosy, were invited to participate in the study. All respondents agreed to participate. Ultimately 38 individuals with uncorrected or surgically corrected ulnar, or ulnar and median palsy due to leprosy participated in the study. They were informed of the study and asked for consent.

Amharic versions of SALSA and DASH, in this study referred as SALSA-am and DASH-am, were developed and used throughout the study. The SALSA scale was translated from English to Amharic, the official language in Ethiopia, in 2006 by two independent translators. According to guidelines,[25] a translation meeting took place with two translators and an interpreter. The common agreed version, the SALSA-am, was used in the study. The translation of the original English version of DASH to Amharic was made in January 2009, where Stages I and II of the Guidelines for the Cross-Cultural Adaptation process for DASH[26] were completed. Two independent translators performed one translation each and followed up the translated versions in a meeting where discrepancies were solved and agreed on in the final version of the DASH-am.

SALSA-am was scored in the same way as the original SALSA version. The lowest score obtained for each question is one (minimum activity limitation) and the highest score four (maximum activity limitation). Thus a total score of 20 is the minimum result and higher scores indicate more severe activity limitations.[8] The DASH-am was scored in the same way as the original DASH version to calculate the patients' 'disabilities' and then convert the score to a scale from 0 to 100, with 0 indicating no disability.

Data collection was undertaken at the ALERT Centre, Addis Ababa, Ethiopia. During an interview, participants were instructed to answer all the questions in both the SALSA-am and DASH-am questionnaires. An additional questionnaire including gender, age, nerve involvement, surgery, profession or work, literacy, WHO Impairment grading[5] and Voluntary Muscle Testing[27] was also completed. A native interpreter, who also spoke English, carried out the interviews even if the participant could read and write. Two of the participants only spoke Oromo, the largest language in Ethiopia. During these interviews, a native Oromo-speaking staff at ALERT provided an oral translation to/from Amharic. While Oromo is

the language that is used by the majority of the population in Ethiopia we considered it important to also include these two in the study. The interpreters were introduced to the Basic Information form and the SALSA-am and DASH-am questionnaires, and the importance of asking the exact questions were explained. The interpreters were also instructed not to interfere with the participants' answers or to guide the participant towards any type of answer. The first author of the study attended all interviews.

For data analysis, SPSS software (SPSS Inc, Chicago, IL) version 19.0 was used. Descriptive statistics were used for patient demographics. Spearman's rank correlation (two-tailed) was used for correlation between SALSA-am and DASH-am scores. Specificity, sensitivity and accuracy for predicting activity limitation were calculated using SALSA-am scores with DASH-am as the gold standard. Limits splitting participants into, high and low activity limitation groups, were based on mean values, and thereafter based on the 25th, 50th and 75th percentiles for SALSA-am and DASH-am respectively.

ETHICAL CONSIDERATIONS

The participants were informed of the aims of the study both in writing and verbally, and all gave their written consent. The local Ethical Committee at ALERT approved the study protocol.

Results

In all, 38 individuals participated in the study (25 men, 13 women; mean age 38 years (range 16–62 years), two left-handed). Twenty five individuals had nerve damage in both their right and left hands. Twenty-four had different secondary impairments. Nearly half of the group, 14 individuals, had surgery on one or both hands (Table 1).

The majority of individuals were farmers or employees of a handicraft workshop for leprosy affected persons (Table 2).

The mean SALSA-am score was 42 (range 23–74, *SD* 12) (Table 3). The highest mean scores for activity limitations were reported for questions: "Do you walk barefoot?" and

Table 1. Description of the examined group

Variable	$n = 38$
Males *n* (%)	25 (66)
Females *n* (%)	13 (34)
Age mean (*SD*)	38 (12)
	(range 16–62 years)
Dominant hand *n* (%) right	36 (95)
Dominant hand *n* (%) left	2 (5)
Nerve impairment *n* (%):	
Nerve impairment both hands *n* (%)	25 (66)
Ulnar nerve right hand *n* (%)	15 (39)
Ulnar + Median nerves right hand *n* (%)	15 (39)
Ulnar nerve left hand *n* (%)	14 (37)
Ulnar + Median nerves left hand *n* (%)	19 (50)
Surgery on one or two hands *n* (%)	14 (37)
Secondary impairments *n* (%)	24 (63)

Table 2. The professions or occupations among the subjects

Profession/occupation	$n = 38$
Farmer	8
Handicraft worker	8
Carpenter	2
Merchant/trader	2
Guard	2
Student	2
Office chairman	2
Beggar	2
Others	7
No answer	3

"Do you walk on uneven ground?" which indicated these were difficult or avoided because of risk. The lowest mean scores were given for questions: "Can you see?", "Do you wash your whole body?" and "Do you work with tools?"

There was a strong correlation between SALSA-am and DASH-am scores using Spearman's rank correlation coefficient where $r = 0{\cdot}87$, $P < 0{\cdot}001$.

Using the mean value for SALSA-am (mean = 42) as cut-off to predict considerable activity limitation, and using the mean value for DASH-am (mean = 32) to evaluate this prediction resulted in an overall accuracy of 84%. The sensitivity was 88% (15 of the 17 individuals with considerable activity limitations according to DASH-am were also classified as having considerable activity limitations according to SALSA-am), with a specificity of 81% (17 of the 19 individuals with no considerable activity limitations according to

Table 3. Range, means and standard deviations of every question in SALSA-am ($n = 38$)

Question	Min	Max	Mean	Std. Deviation
1. Can you see?	1	3	1·45	0·60
2. Do you sit or squat on the ground	1	4	2·05	1·21
3. Do you walk barefoot?	0	4	3·11	1·25
4. Do you walk on uneven ground?	1	4	2·68	1·09
5. Do you walk longer distances?	0	4	2·45	1·22
6. Do you wash your whole body?	1	4	1·53	0·92
7. Do you cut your finger or toe nails?	0	4	1·92	1·15
8. Do you hold a cup or basin with *hot* contents?	0	4	2·61	1·22
9. Do you work with tools?	1	4	1·58	0·95
10. Do you carry heavy objects or bags?	1	4	2·50	1·13
11. Do you lift objects above your head?	1	4	2·55	1·11
12. Do you cook?	0	4	2·13	1·53
13. Do you pour hot liquids?	1	4	1·89	1·16
14. Do you open/close screw capped bottles?	1	4	1·84	0·86
15. Do you open jars with screw-on lids?	1	4	2·21	1·12
16. Do you handle or manipulate small objects?	1	4	1·76	0·94
17. Do you use buttons?	1	4	1·82	1·04
18. Do you thread needles?	1	4	2·24	1·20
19. Do you pick up pieces of paper, handle paper or put it in order?	1	4	1·61	0·82
20. Do you pick up things from the floor?	1	4	1·63	0·85
SALSA Total	23	74	41·55	11·63

Table 4. Specificity, sensitivity and accuracy for predicting activity limitation using SALSA-am scores with DASH-am as the gold standard. Limits splitting participants into high and low activity limitation groups, were based on mean values, and thereafter based on the 25th, 50th and 75th percentiles for SALSA-am and DASH-am respectively. N_{SALSA} and N_{DASH} indicate number of participants with poor prognosis

Limits	$N_{SALSA\text{-}am}$	$N_{DASH\text{-}am}$	SALSA-am limit[1]	DASH-am limit[2]	Sensitivity	Specificity	Accuracy
Mean	19	17	42	32	88%	81%	84%
25th percentile	29	29	30·75	17·54	93%	78%	89%
50th percentile	19	19	42	27·59	89%	89%	89%
75th percentile	10	9	50	47·71	67%	86%	82%

[1] The score for the patient with the lowest SALSA-am score among the N_{SALSA} patients with the highest SALSA-scores

[2] The score for the patient with the lowest DASH-am score among the N_{DASH} patients with the highest DASH-scores

DASH-am were also classified having no considerable activity limitations by SALSA-am). Other cut-off values were also examined (Table 4).

Discussion

The aim of the current study was to evaluate the validity of the SALSA-am questionnaire using DASH-am as the gold standard. The correlation between SALSA-am and DASH-am was strong (correlations $>\cdot 70$ can be considered strong[12,28]), and by using the mean values as cut-offs to predict considerable activity limitation, the results indicated high sensitivity, specificity and accuracy. Based on this, it can be concluded that SALSA-am has high criterion validity when using DASH-am as a gold standard.

The SALSA questionnaire covers activity areas such as mobility (feet), self-care, work (hands) and dexterity (hands). Fifteen of the questions include aspects of hand activities, while the remaining five concern activities that often imply problems for people with affected sensibility in other body areas. In the DASH questionnaire, 21 questions are about hand activities, three are about social participation and the remaining six are about pain, weakness or stiffness. The five answer alternatives in DASH grade problem severity in each activity. In SALSA, however, each activity is graded twice. The respondent decides whether the questioned activity is a problem or not, and also has to make clear why the activity is not performed. Here, the safety awareness appears in the alternative "I avoid because of risk."

A major benefit of SALSA is that in order to be as valid as possible, the activities are chosen from the culture and environment where the participants live. DASH, on the other hand, is developed for use in Western culture. Therefore DASH consists of questions regarding activities that are less common in the respondents' environment, despite cultural translation. SALSA was developed for the investigated population (people with neuropathy due to leprosy or diabetes) and has been repeatedly evaluated in expert groups using both focus groups and individual interviews.[8]

The most commonly used aspects of validity are *face*, *content*, *criterion-related* and *construct validity*.[28–32] In development of an assessment the different forms of validity should be tested specifically.[29] One part is to test the criterion-related validity, which means

to what extend the measurements of the assessment correlate to some other, already validated measurement. It is an objective and practical approach in the validity concept. A sub concept to criterion-related validity is *concurrent validity*, which evaluate the correlation between the new assessment that are tested and an already existing one, used as a *gold standard*. The assessments or questionnaires are given to the same subjects at the same time so that the both tests reflect the same situation.[29–32] One difficulty when testing the concurrent validity is to find a criterion that reaches the gold standard and is reliable and valid in itself.[28] DASH was developed for North American or Western Standards, which can complicate the translation both in terms of language and culture. Nevertheless, it is a well-tested questionnaire which has been translated into several languages and cultures, and both its validity and reliability have been tested for a variety of upper extremity diagnoses.[12,15–23] DASH has also been used for testing the construct validity of another assessment tool using correlations.[33,34] Zimmerman *et al.*[24] consider the DASH questionnaire as *criterion standard* for testing the criterion validity in another questionnaire. Thus, for the purpose of this study DASH was considered the best available criterion standard.

The activity limitations highlighted as the most common from the SALSA-am results were walking barefoot or on uneven ground. Walking is the main way of transporting oneself in Ethiopia, and with loss of sensation in the foot, blisters and infected wounds frequently occur. The least problems were reported for vision; whether the respondents could wash their whole body, or if they could work with tools. Surprisingly, tool work was not stated to be a big problem even when both sensibility and motor functions were affected. This result may be connected with the respondents' good vision. Blindness occurs at a late stage of leprosy, and if treated in time can be avoided.[2,5–7] The loss of sensibility can be partly compensated for with intact vision. Of the 38 participants, 14 had undertaken some kind of reconstructive surgery and this may also have had an impact on the motor function and grip ability of the hand. Surgery cannot repair damaged nerve function and sensibility, but can compensate for loss of movements and restore grip through tendon transfers.[33–36] The majority of respondents worked as farmers. One said he was a former farmer but currently did not have an occupation and spent a lot of time at the hospital for wound care. Another said he wanted to be a "shoe-shiner" but he had difficulties performing this task with both ulnar and median nerves affected in both hands. He thought it would be hard to get customers. Several women in the group worked at a handicraft workshop in the ALERT compound or at one just outside the compound. Both these workshops ran projects helping individuals with physical and visual impairments to earn an income when they would otherwise find it difficult to gain employment due to the stigma of their disabilities. The stigma around leprosy and leprosy-related disabilities restricts the individual in society.[2,7,9–11] Societal values have a big impact on people with a disability. Family and social groups in which the individual used to be involved may change dynamics. The roles the individual used to have, and found themselves identifying with, can diminish or dramatically change.[37] Perhaps it is not the impairments or activity limitations that are the greatest problem for the affected person, but the stigmatising participation restriction it leads to. Boku *et al.*[9] suggest participation restriction due to stigma can be more important than the underlying health condition.

STUDY LIMITATIONS

The majority of interviews were performed with one external interpreter, but several interviewers were involved in the study. Some of them only made one interview. The multiple

interviewers involved may have had a negative effect on the quality of data. However, the two original versions of the questionnaires are standardised with high intra- and inter-tester reliability.[17,22,29,38] To minimise the negative effects, the interviewers all received information about the study and the questionnaires.

Another limitation of the study is that neither SALSA-am nor DASH-am were back-translated to English from Amharic as recommended for example by the Guidelines for the Cross-Cultural Adaptation process.[25–32] This may have affected the concepts used in the Amharic versions and a back translation is suggested in further validation of the SALSA-am.

Two of the participants were not native Amharic speakers. Since part of the potential patients in Ethiopia being assessed using SALSA-am do not have Amharic as their native language, but will instead be asked the questions based on a translation from Amharic to Oromo, it can be considered relevant to include these in the analysis. To be on the safe side though, a re-analysis controlling for the two participants with Oromo as their native language was performed. During anonymisation of the responses the notes of which two participants were not native Amharic speakers were lost. For each statistical test the two participants with most interfering patterns (compared to results where all participants were included) were excluded and the analyses were recalculated. However, in no such re-analysis the results were affected in such a way that results were altered. Therefore results based on the whole sample were reported. The exact values might of course differ somewhat.

Conclusions

The SALSA-am questionnaire is a useful tool for grading the effect of disabilities in leprosy and is highly correlated to the DASH-am questionnaire. The concurrent validity in SALSA-am is good when DASH-am is used as the criterion or gold standard. According to DePoy and Gitlin[29] the different forms of validity should be tested specifically and a single study is not sufficient to determine an assessment's validity. This study is a part of the validation of SALSA-am. SALSA-am can be a useful tool in planning and evaluating clinical interventions and programmes for the prevention of disability in leprosy-affected people.

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