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Title: Validation of the Nepali version of the self-reported Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) in adults with chronic pain and predominantly low-literacy levels

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Running title: The SLANSS validation in Nepal

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ABSTRACT

Neuropathic pain research and clinical care is limited in low-income countries with high prevalence of chronic pain such as Nepal. We translated and cross-culturally adapted the S-LANSS—a commonly used, reliable and valid instrument to screen for pain of predominantly neuropathic origin (POPNO)—into Nepali (S-LANSS-NP) and validate it using recommended guidelines. We recruited 30 patients with chronic pain in an outpatient setting for cognitive debriefing and recruited 287 individuals with chronic pain via door-to-door interviews for validation. For known-group validity, we hypothesized that the POPNO group would report significantly more pain intensity and pain interference than the chronic pain group without POPNO using a cut-off score of ≥10/24. The S-LANSS-NP was comprehensible based on the ease of understanding the questionnaire and lack of missing responses. The validation sample consisted of predominantly low-levels of literacy (81% had five years or less education); 23% were classified as having POPNO. Internal consistency was good (alpha=0.80). Known-group validity was supported (chronic pain with POPNO reported significantly greater pain intensity than those without). The S-LANSS-NP is a comprehensible, unidimensional, internally consistent, and valid instrument to screen POPNO in individuals with chronic pain with predominantly low-levels of literacy for clinical and research use.

PERSPECTIVE

This paper shows that the Nepali version of the S-LANSS is comprehensible, reliable and valid in adults with chronic pain and predominantly low-levels of literacy in rural Nepal. The study could potentially develop research and clinical care of neuropathic pain this resource-limited setting where chronic pain is a significant problem.

KEYWORDS

Neuropathic pain; Chronic pain; Musculoskeletal pain; Reliability; Nepal
INTRODUCTION

About one quarter of the world’s population experience chronic pain with a significant proportion with neuropathic origin.\textsuperscript{10, 20} Population prevalence estimates of chronic pain with neuropathic characteristics range from 3\% to 17\%.\textsuperscript{57} Most of these estimates are derived from developed countries; prevalence estimates of neuropathic pain (NeuP) from developing countries are lacking.\textsuperscript{42} NeuP is generally more intense and causes greater pain-related interference than non-neuropathic chronic pain,\textsuperscript{53} and requires different pharmacological approaches to management.\textsuperscript{23, 51} Identification of any neuropathic component to pain is important to inform management and reduce its adverse impact on individuals and society. However, non-specialists can find diagnosis of NeuP difficult, with potential delays in evidence-based management.

NeuP is commonly diagnosed using clinical criteria such as characteristics of pain (e.g. burning, tingling), or presence of allodynia and hyperalgesia.\textsuperscript{26, 27, 36} Several self-reported measures are available in English to facilitate screening or identification of NeuP, such as the S-LANSS (self-report version of the Leeds Assessment of Neuropathic Symptoms and Signs), and the DN4 (\textit{Douleur Neuropathique en Quatre Questions}).\textsuperscript{4, 7, 30} The advantage of self-report questionnaires is that they can be used in postal and telephone surveys, without the need for clinical assessment.\textsuperscript{8} Each has its own strengths and weaknesses with varying measurement properties.\textsuperscript{37}

The S-LANSS is a commonly used reliable and valid instrument to screen for the possibility of NeuP.\textsuperscript{58} It has acceptable diagnostic accuracy with sensitivity ranging from 72\% to 89\% and specificity ranging from 77\% to 95\%.\textsuperscript{5, 8, 15, 33, 35} It has been used in large population-level surveys to estimate the prevalence of pain of predominantly neuropathic origin (POPNO).\textsuperscript{8, 53, 56, 58, 60} Internal consistency ranges from acceptable to good (Cronbach’s alpha: 0.71 to 0.81) for self-completion or completion via interviews.\textsuperscript{8, 33, 35} Only Spanish version of the SLANSS has tested its dimensionality in a sample with chronic pain and found
it to be unidimensional. It has also been translated into numerous languages including Arabic, Spanish, Turkish, Polish, and Greek and has been used in different clinical populations including chronic pain, diabetic neuropathy, post-herpetic neuralgia, and stroke. However, it has not yet been validated in a sample with low-levels of educational attainment. This is important because 773 million adults globally cannot read or write limiting applicability of screening instruments in these people.

A South Asian lower-middle income country, Nepal, has an illiterate population of about 10 million (i.e., one third of the population). Over 80% of the population live in rural communities and more than a quarter live below poverty line. Understanding pain in these rural communities with low socioeconomic conditions may provide a unique insight into POPNO in those with low socioeconomic conditions. Not being able to read and write also affects one’s ability to complete self-reported scales such as the S-LANSS, limiting the ability to screen for the diagnosis of POPNO.

Therefore, translation and cross-cultural adaptation of the SLANSS into Nepali, and its validation would facilitate: (1) identification of POPNO in individuals with (chronic) pain and therefore, potentially improve its management and outcome; (2) epidemiological studies on NeuP prevalence, distribution and progression; and extending the generalisability of the SLANSS validation in those with lower levels of education.

The aims of this study were to translate and cross-culturally adapt the S-LANSS into Nepali and assess its internal consistency and known-group validity in a sample of individuals with predominantly low-levels of educational attainment. We hypothesized that the Nepali S-LANSS (S-LANSS-NP) would be comprehensible and would demonstrate acceptable internal consistency, in agreement with use of the S-LANSS in other populations. Finally, and consistent with the original design and implementation of the S-LANSS, we hypothesized that individuals testing positive on the S-LANSS-NP (i.e.
score ≥10) would report significantly greater pain intensity and pain interference compared to those with pain who tested negative (score<10).

METHODS

We conducted the study in two phases. In Phase 1, we translated and cross-culturally adapted S-LANSS into Nepali. In Phase 2, we assessed its measurement properties (internal consistency and known-group validity), and examined the clinical characteristics associated with positive scores.

Phase 1: Translation and cross-cultural adaptation

Translation steps

We followed international recommended guidelines to translate S-LANSS into Nepali. We have used a similar approach to translate other patient-reported outcome measures into Nepali in the past and yielded acceptable measurement properties. We completed the translation using the following steps.

The original developers of the S-LANSS first provided official permission to translate the S-LANSS into Nepali. Then, two native Nepali speakers (a physiotherapist, and a non-medical translator) independently forward-translated the original English version of the S-LANSS into two Nepali versions. The two translators then reconciled the forward translations (T1 and T2) in collaboration with two study authors (IB and SS) to create a single reconciled Nepali version (T3). Two new bilingual translators, naïve to the study aims and original S-LANSS, then back-translated the T3 version into English (T4 and T5). We then formed a panel of experts which included all of the translators and one of the study authors (IB), who discussed all versions of the scale and confirmed a pre-final version of the Nepali version of the S-LANSS.

One of the study authors, SS served as a methodologist throughout the translation process based on his experience of translation and cross-cultural adaptation studies.
One of the original developers of the S-LANSS, BHS (a native English speaker, also a co-author in this study), then provided input into the back-translated versions of the final translation. BHS, along with another developer of the original S-LANSS, MB (also a co-author), reviewed and approved the final back-translated version of the final Nepali version of the S-LANSS.

Cognitive debriefing

Following the completion of translation, we performed cognitive debriefing in 30 patients with chronic pain at the Outpatient Department of Physiotherapy, Dhulikhel Hospital, Nepal in March 2019. Between 5 and 40 participants are required to perform cognitive debriefing based on the guidelines used or instruments being tested, and a sample size of 7 or more is considered sufficient by the COSMIN recommendations for content validity. The main aim of the cognitive debriefing was to test the comprehensibility, where participants were asked the meaning of each item, and whether items reflected the meaning in the original English version of the scale. Comprehensibility is one important aspect of content validity of patient-reported instruments, the most relevant to translation of an instrument.

One of the study authors, IB, administered the questionnaire in an interview format for all the cognitive debriefing participants. IB is has a Master of Physiotherapy Degree in Community Rehabilitation and has over a decade of experience in conducting qualitative interviews. IB first conducted in-depth interviews all interviews in two sets of 15 participants in each set. The comments and feedback in the first set of interviews were incorporated in the revised version of the S-LANSS was tested in the second set of 15 participants.

Phase 2: Validation study

Study design and setting

The current cross-sectional study was part of a study exploring the characteristics and management of chronic pain in rural communities in Nepal. Trained senior
physiotherapy students, who served as research assistants, collected data via a door-to-door survey.

The study site was a rural Baluwa village of the Panchkhal Municipality, in the Kavre district of Province 3, Nepal. Ward number 10 was selected for data collection (non-probability sampling). It has a total of 210 households with a total population of 1,115 people. Over 70% of households belong to caste/ethnic group of Brahmins and Chettris. Although Baluwa is located only about 40 kilometers east of Kathmandu, it is remote because of geographical and developmental barriers. Adults in all households of Ward 10 Panchkhal Municipality were approached for the survey.

Most members of this community live with low socioeconomic status including low educational and literacy levels, and this limits participation in research via postal surveys. Access to cell phones and the internet is also poor. The most feasible approach to data collection in this sample was therefore a door-to-door survey, as we and others have used in previous research in Nepal.

Procedures

An experienced study author, IB, trained the research assistants to conduct door-to-door surveys to collect data and administer the S-LANSS. IB has 14 years’ experience of conducting community research including door-to-door survey. The training involved six days of training; four days were exclusively allocated for training research assistants to collect data. The training also included “mock” data collection sessions providing opportunities to ask questions in order to standardise data collection procedures. Student researchers have successfully and reliably collected data using door-to-door surveys in previous research in rural Nepal.

Research assistants presented at every doorstep in the village, explained the aims of the study, and invited any eligible residents currently living in the village and with chronic pain to participate. If the potential participants were eligible (see eligibility criteria below),
research assistants obtained written informed consent from all participants who provided data. If the potential participants could not sign, a verbal consent was obtained and a witness signed on their behalf. This survey was integrated within the community research requirement for the fulfilment of the Bachelor of Physiotherapy degree at Kathmandu University School of Medical Sciences. The study protocol was approved by the Institutional Review Committee of Kathmandu University School of Medical Sciences, Dhulikhel, Nepal (ethics approval number 121/19).

**Study participants**

All members of the community were deemed eligible if they: (1) were resident in Baluwa village; (2) experienced chronic pain (pain lasting for three months or longer) at the time of screening; (3) were 18 years or older; (4) could communicate fluently in Nepali; and (5) were able to provide written or verbal consent to participate in the study. Participants were excluded if they were not able to communicate in Nepali, or if they had a health condition (e.g., dementia) that limited their ability to answer to research questions. Dementia was screened based on a self-report or as previously diagnosis by a physician. We did not use formal screening tools such as Mini-Mental State Exam to screen dementia in this study because they tend to overestimate dementia or cognitive decline in those with low-educational levels. Participants who could not read and/or write were included in the study to improve the generalizability of the study as over one quarter of Nepal’s population is illiterate. All data were collected in March 2019. The participants involved in Phase 1 were not recruited in this phase.

**Measures**

**Socio-demographic and pain-related questions**

Socio-demographic questions included sex, marital status, religion, ethnicity/caste, occupation, and education. Pain-related questions included duration of pain measured in months of ongoing pain, and location of pain assessed using pain drawings. Musculoskeletal pain was identified based on each participant’s self-report and identification of the site of
pain on the pain drawings.\textsuperscript{47, 48} Multiple sites of pain were identified based on participants’ reports of pain in more than one body region on the pain drawing.

**Self-reported Leeds Assessment of Neuropathic Signs and Symptoms**

The S-LANSS is a commonly used self-reported screening tool to assess signs and symptoms related to NeuP.\textsuperscript{8} It can be administered using self-report or interview methods (e.g., via telephone interviews). It has been shown to have sufficient reliability and validity for use in epidemiological studies.\textsuperscript{8, 15, 33, 35} It has seven items with a total score ranging from 0 to 24. A cutoff score of 10 or more is considered an optimal cutoff point to indicate presence of POPNO when completed via interviews.\textsuperscript{8}

**Numerical Rating Scale (NRS)**

The eleven-point Numerical Rating Scale (NRS) embedded within the S-LANSS was used to assess pain intensity over the previous 7 days. Higher scores indicate greater pain intensity, with scores ranging from 0 (No pain) to 10 (As severe as it could be). The Nepali translation of NRS is reliable, valid, and responsive.\textsuperscript{45}

**Pain Intensity version 1.0 short form 3a**

The Nepali translation of the Pain Intensity short form 3a includes three items and is shown to be comprehensible, reliable, and valid.\textsuperscript{41, 49} It assesses three aspects of pain intensity: worst pain in the past week; average pain in the past week; and current pain.\textsuperscript{13} Participants are asked to rate their pain intensity using a five-point Likert scale ranging from 1 to 5, where 1 = Had no pain, 2 = Mild, 3 = Moderate, 4 = Severe, and 5 = Very severe. Higher scores indicate greater pain intensity.\textsuperscript{13, 28}

**Pain Interference version 1.0 short form 6b**

The Nepali translation of the PROMIS Pain Interference short form 6b includes six items and is shown to be comprehensible, reliable and valid.\textsuperscript{41} It assesses the self-reported consequences of pain on social, cognitive, physical, and recreational activities.\textsuperscript{1} Participants are asked to rate the extent to which their pain interferes with daily functioning in each of the...
six items using a five-point Likert scale ranging from 1 to 5, where 1 = Not at all, 2 = A little bit, 3 = Somewhat, 4 = Quite a bit, and 5 = Very much. Higher scores indicate greater pain interference.¹

**Statistical analysis**

Internal consistency of the S-LANSS-NP was assessed using Cronbach’s alpha. We considered values of Cronbach’s alpha <0.70 as inadequate, values from 0.70 to 0.79 as adequate, values from 0.80 to 0.89 as good, and values ≥0.90 as excellent.¹⁶

We performed exploratory factor analysis to test the dimensionality of the scale using Principal Axis Factoring and Direct Oblimin rotation to allow correlation between the potential factors. We recorded the total variance explained by the factors. Scree plot was used to indicate the number of factors extracted (i.e. based on Eigenvalues more than 1). Factor matrix was used to record the factors extracted with the loading of each item.

To test known-group validity, we performed independent sample t-tests with unequal variance assumed (or Welch’s unequal variance t-test) for the mean scores of pain intensity in the two scales described above and pain interference separately for the group that was categorized as having POPNO (S-LANSS-NP score ≥10) and those without POPNO (S-LANSS-NP score <10). A cut-off score of ≥10/24 was used because it has been shown to accurately discriminate POPNO from those without for screening via interviews. It was hypothesized that the POPNO group would report significantly more pain intensity and pain interference than the group without POPNO.¹⁶ We considered p<0.05 a threshold for significance a priori. Observations with missing responses were excluded from all analyses.

All statistical analyses were performed in IBM SPSS Statistics for Windows, Version 26.0 [Armonk, NY: IBM Corp].
RESULTS

269 Phase 1: Translation and cross-cultural adaptation

The S-LANSS was translated into Nepali successfully. The instructions were easy to translate and understand. The right anchor of the numerical rating scale embedded in the S-LANSS was initially translated as “ugra dukhai” which translates as “severe pain”. Later, it was changed to “atyadhik dukhai” which also means “severe pain” or “maximum pain” because this anchor has been validated in a Nepali translation of a Numeric Rating Scale.45 Five of the seven items were translated without difficulty or the need to revise. Two items (items 4 and 7) needed an in-depth discussion and consulting with the remotely located expert committee members (SS and BHS). The descriptor “jumping” in item 4 was first translated as “buluk buluk” which back-translates to a “throbbing” kind of pain rather than “jumping” pain.47 This then was changed to “shola haneko” which closely relates to pain that comes and goes, similar to shooting pain. In item 7, the use of “tenderness” in the response option was initially translated into Nepali as “komal” which means “soft”. However, after discussion with the extended expert committee members, it was changed to “dukhai” “painful (to touch)” to reflect a more accurate translation because a single Nepali word to describe the intended meaning of “tenderness” does not exist. Minor changes to sentence structures and grammar were made before finalizing the questionnaire for cognitive debriefing. The cognitive debriefing sample consisted of 30 adults with chronic pain (mean age 47.7 (SD 13.5) years). Eighty-one percent had no formal education or had a maximum of five years of primary school education. The sample is completely described in Table 1.

After the first set of cognitive debriefing interviews, minor changes in sentence structure and grammar were made. After incorporating the feedback, the remaining 15
participants in the second set did not have any new comments. There were no missing or multiple responses.

The SLANSS-NP was therefore deemed comprehensible because all stakeholders involved (questionnaire translators, study authors, and cognitive debriefing participants) understood the intended meaning of the instruction, items, and response options. The S-LANSS-NP is available in Appendix 1. It was then used in the larger community sample to test its internal consistency and known-group validity in the Phase 2 study.

**Phase 2: Validation study**

A total of 542 participants were approached and screened for the presence of chronic pain via door-to-door interviews. Two hundred and eighty eight of 542 (53%) met the criteria for inclusion with the presence of ongoing chronic pain. All but one of these participants (n=287; 99.7%) completed the S-LANSS-NP, forming the sample for the analysis of measurement properties. Using the S-LANSS-NP for diagnosis, 66 participants were categorised as having POPNO. This is 12.2% of the total community sample screened and 23% of those with chronic pain. Details of sociodemographic and pain related characteristics are presented in Table 1 and summarized below.

**Demographic characteristics**

The mean age of the included participants was 51.1 years (SD 16.3). The majority of participants (69%) were women and 55% never attended a school.

**Pain characteristics**

The predominant type of pain was musculoskeletal (58%) based on participants’ self-report. The most commonly reported site of pain was the knee and leg (24%), followed by multiple sites (pain located in more than one location; 17%) and head (12%). Reported average duration of chronic pain was 36.7 (SD 45.6) months.
Reliability

Internal consistency was good (Cronbach’s alpha = 0.80).

Factor analysis

Exploratory factor analysis identified a single factor. The factor loading (see Table 2) of each item ranged between 0.428 (Item 2) to 0.808 (Item 7). Scree plot showed a single factor (Figure 1). This single factor explained 50% of the total variance.

Known-group validity

Data for pain intensity and pain interference were both normally distributed. We found that individuals with POPNO reported significantly greater pain intensity compared to the non-POPNO group (see Table 3). The difference in pain interference, however, although higher in the POPNO compared to non-POPNO group, was not statistically significant.

DISCUSSION

We found that the S-LANSS-NP was comprehensible and demonstrated good internal consistency in an adult Nepali sample from rural Nepal. We also found partial support for known-group validity—participants with POPNO (based on the predetermined S-LANSS cutoff) presented with significantly greater pain intensity than those without POPNO; however, there was no group difference concerning pain interference. The prevalence of POPNO is comparable to the prevalence of POPNO reported previously i.e. between 7% to 10% in the general population and between 20% to 25% in those with chronic pain which is comparable to our findings. Our findings also coincide with the findings of a recent systematic review which reported a 23% prevalence of neuropathic pain in individuals with knee osteoarthritis.
The first finding relating to comprehensibility fits well with the existing literature describing its successful translation into several other languages. Among the languages spoken in Asian countries, S-LANSS has been translated into Arabic and Turkish. However, Nepali is the first South-Asian language into which the S-LANSS has been translated, to the best of our knowledge. This translation can help epidemiologists to estimate the prevalence and distribution of NeuP in Nepali speaking communities. The second finding relating to internal consistency of S-LANSS-NP was well within the range previously reported and as hypothesized. The results indicate that the S-LANSS-NP items are strongly interrelated, contributing to reliable overall screening of neuropathic signs and symptoms.

The S-LANSS-NP demonstrated unidimensionality similar the Spanish translation. The dimensionality of the S-LANSS has not been tested in the original English version nor on other translated versions. The original English version of the clinician-reported LANSS has been tested for its dimensionality and found conflicting results. While it demonstrated unidimensionality for chronic postsurgical pain and diabetic neuropathy, the results could not be replicated in the samples with osteoarthritis, low back pain and musculoskeletal injuries. Its dimensionality may be tested in other samples and translated versions.

The final finding relating to known-group validity was supported based on pain intensity findings but not pain interference. Previous studies have reported that individuals with POPNO report significantly greater pain intensity than those without POPNO. The mean difference in the numerical rating scale exceeds its acceptable minimum important change score of 1 of 10 points. One possible explanation for the lack of difference found in pain-related interference is that the majority of included participants were farmers and from lower socioeconomic conditions, whose economic circumstances meant that they had to continue their work and daily activities irrespective of their pain levels. Despite the lack of difference found in pain interference between participants with and without POPNO, significantly greater pain intensity in the POPNO group compared to those
without indicates its greater severity of chronic pain associated with POPNO. Greater physical functioning despite severe pain intensity is well reported among people living with pain conditions in rural Nepal.²

These findings are important in advancing research and clinical care for NeuP in Nepal. We showed that S-LANSS was comprehensible in a rural sample of Nepali people with very low levels of education (81% had less than 5 years of education). This is a novel finding and a strength, as it adds to the generalizability of the study findings to the majority of the population of Nepal, where low-literacy levels are reported nationally.¹⁴ As the S-LANSS has the advantage of being administered using self-report or interview methods,⁶ it can be used in population-level epidemiological studies on NeuP or POPNO prevalence and distribution, which are currently lacking from Nepal. It can also potentially be used in telehealth consultations, supported by its successful use in previous research utilizing the telephone as a screening medium.⁸ This is especially important in rural communities of Nepal with difficult geographical access but improving access to mobile phones and internet.¹⁸ Assessing the feasibility of its use in telehealth for screening of POPNO however warrants further research.

The current study should be interpreted cautiously considering its limitations. First, we were unable to assess longitudinal reliability (test-retest reliability) because of the cross-sectional nature of the available data. Future work on test-retest reliability is needed. Secondly, we did not assess discriminant validity (i.e., sensitivity and specificity) because research assistants collected all data in a rural community with limited resources. Second, reference standard clinical assessments by experienced clinicians were not feasible. We were also unable to assess construct validity using hypothesis testing because of unavailability of other instruments to assess neuropathic pain (such as DN4 and Pain-DETECT) in Nepali. Although they had adequate skills to interview participants, they were not sufficiently trained to correctly categorize any pain as neuropathic or non-neuropathic based on clinical evaluation. Despite this, there is no reason to suppose that the sensitivity
and specificity in this population would be greatly different from those tested previously. There is support for data collected using interviews, (as done here) having better sensitivity and specificity than those collected by the self-completion method. Future studies may assess the sensitivity and specificity of the S-LANSS-NP using trained clinicians, although there are challenges with this in resource-poor settings.

Third, for the known-group validity, we did not plan to control for common covariates such as gender and age a priori. However, on a post-hoc analysis of covariance test by adjusting for gender and age did not change the study results. Forth, we purposively chose Baluwa village and missed potential participants who were not available during the door-to-door surveys and dalit/tamang and other ethnic/caste groups in cognitive debriefing. These can affect the generalisability of S-LANSS to all Nepali individuals. Future epidemiological studies should consider random sampling of the villages and participants from each village to improve generalisability of the study findings. Finally, only 66 people met the criteria of POPNO which formed the sample for testing validity. Although 100 or more participants are considered ideal for testing validity, the COSMIN guidelines recommend a sample size of 50 to 99 as “adequate” for establishing measurement properties.

The Nepali translation of S-LANSS was comprehensible, internally consistent, and valid among individuals with predominantly low-literacy levels and chronic pain in rural Nepal. It can, therefore, be used in clinical settings and larger epidemiological studies to identify pain of predominantly neuropathic origin in individuals with chronic pain in Nepal.

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