# Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE DOI: 10.53555/jptcp.v31i8.7479

## URDU TRANSLATION, VALIDITY & RELIABILITY OF LEADS ASSESSMENT OF NEUROPATHIC SYMPTOMS AND SIGN PAIN SCALE (LANSS) QUESTIONNAIRE

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#### **ABSTRACT**

#### **Background:**

The LANSS questionnaire is used for the assessment of neuropathic pain and examination of functional outcomes of the physical therapy treatment following neuropathic pain. This questionnaire exhibited significant characteristics as an assessment for patients with neuropathic pain.

## **Objective:**

To translate the Leads Assessment of Neuropathic Symptoms and Signs Pain Scale (LANSS) in Urdu and determine its Validity & reliability through characteristic properties.

## **Methodology:**

In this descriptive cross-sectional study, a non-probability purposive sampling technique was used to assess 70 neuropathic patients for the LANSS questionnaire. The Participants were asked to fill out the Leads Assessment of Neuropathic Symptoms and Signs Pain Scale (LANSS) and Douleur Neuropathic 4 Questionnaire (DN4), VAS, Barthel index. The data was collected on the first clinical day and the second and third follow-up days.

#### **Results:**

The results revealed that the test-retest reliability for LANSS is sustainable. The overall outcome depicts that the reliability coefficient for LANSS (ICC=0.83, CI=95%) is good.

#### **Conclusion:**

The Urdu-translated version of LANSS is valid and reliable for the assessment and evaluation of neurological symptoms in clinical examination.

**Keywords**: Douleur neuropathic 4 questionnaires (DN4), Leads assessment of neuropathic symptoms and signs pain scale (LANSS), Barthel index, visual analog scale, neuropathic pain.

#### INTRODUCTION

Any lesion or disease affecting the somatosensory system affecting 7–10% of the population results in Neuropathic Pain.(1). According to present estimates, around 1.5% of the general population in the US is suffered from Neuropathic Pain. Bowsher has also reported that some form of Neuropathic pain is affecting at least 1% of the UK population.(2)

In the Netherlands, with age the incidence of neuropathy increases. About 100,000 people are in age of <50 years while >75 years old age people having diabetes are about 32% of all the presenting cases.(3)While in Asia Neuropathic prevalence is 3.2% and out of it, 30% population is affected by neuropathic pain in Pakistan.(4). Increased blood glucose (BG) levels, high triglycerides (TG) normal range, Obesity, smoking, and high blood pressure are considered contributing factors for neuropathy.(5).

There are many tools available for the evaluation of neuropathic pain. Validated tools among them for neuropathic pain are the Douleur Neuropathic-4 Questionnaire, Pain Detect, Leeds Assessment of Neuropathic Symptoms and Signs Pain Scale and Self-Administered LANNS, and ID-Pain. These are considered as objective tools worldwide having cutoff points. Besides these, there are some other tools available for neuropathic evaluation.(6)

LANSS is used to rule out neuropathic patients having complex pain conditions.(7). Sensory description or the examination of sensory dysfunction is done through the LANSS scale. DN-4 is helpful in the early detection of patients that are at risk of developing neuropathic pain, While The LANSS first part contains five dichotomous symptoms related items related to pain experienced by a patient in the last week. The Second part is used by health care professionals for the presence of allodynia and altered pin prick threshold. Marking of each item is done as present or absent, and the presence of each item has given a different score. A score of 12 and greater than this out of 24 scores is considered neuropathic pain.(8)

#### METHODOLOGY

The study design used in this study was descriptive cross-sectional. The sample size was calculated through the bonnet formula and sample size was 70. The duration of the study was 6 months after the approval of the research Ethical Committee. Non-probability purposive sampling technique was used for sampling. The data was collected from Rawal General Hospital, Pakistan Atomic Energy Commission (PAEC), and Pakistan Institute of Medical Sciences (PIMS). Inclusion criteria of this study was participants with over 18 years of age, patients diagnosed to have neuropathic pain (NP) were also included and patients who had an understanding of the questionnaire were included and written informed consent was obtained. Participants in this study were excluded on basis of following criteria: - Possible and non-neuropathic pain in patients was not included in the study and Patients of cognitive impairment and Patients having neurological and musculoskeletal complications.

LANSS is a 7 items tool used for neuropathic evaluation. Out of these, five are symptoms related and two include the clinical examination. The Score of 12 and greater than this suggests neuropathic pain in patients.

The Barthel Scale/Index (BI) is a scale used to assess the performance of a particular person in ADL (activities of daily living). Variables that are ten in number are interpreted and describe mobility and ADL, are recorded, a higher number, higher will the ability to perform functions independently and is a standard set for the approval of hospital discharge.(9)

A Visual Analogue Scale (VAS) is a measurement tool used to assess a trait or attitude that is not possible to measure directly. It is a horizontal line of 100mm in length, with word descriptors at either end. The VAS score is measured in millimeters from the line's left-hand end to the patient's mark.(10). Participants were provided written, informed consent before data collection to meet inclusion criteria participants will be clinically stable and able to read the Urdu version of LANSS. The patient response

was checked on translated Urdu version of LANSS on three points. First on the first day of clinical rotation and then on the second and third days of follow-up for test-retest reliability.

DN4 is a clinician-administered questionnaire that contains ten items related to symptoms and clinical examination. A total score of 4 or more (total of 10) suggests neuropathic pain.

By using JPMA guidelines for cross-culture adaptations LANSS questionnaire was translated into Urdu through these steps. Forward translation, Synthesis-I, Blind Backward translation with reconciliation, Synthesis-II, Cognitive debriefing (Pilot test). (11)

Data was analyzed using SPSS version 21. Statistical analysis includes demographic evaluation and calculation of validity and reliability. The Validity of translated tool is analyzed using face validity, content validity, and construct validity. Face validity and content validity determined by experts were separately analyzed. CVI calculation was done on an excel sheet. The Correlation of LANSS and, Barthel index, and VAS is determined using Pearson's correlation. Construct validity is determined using factor analysis. Test-retest reliability is determined using the Interclass correlation coefficient.

#### **RESULTS**

The translated final version of LANSS was reviewed by the expert panel (having clinical experience of more than 10 years) on a dichotomous scale for face validity. Content validity is present with relevance scale and content validity index (CVI). Pretesting was done on 10 patients. Data was collected on Urdu final version LANSS on three points. One on the first day of clinical rotation, the second on the second follow-up day, and the third on the third follow-up day.

A total of 70 participants were initially enrolled in the study, and all completed the respective tests on the first day of clinical rotation, the second follow-up day, and the third follow-up day. The values of DN4, Barthel index, and VAS of Pain were taken on the first day of clinical rotation, the second follow-up day, and the third follow-up day. Face validity was marked by the experts on a dichotomous scale having two options "YES" and "NO". The Likert scale and symbol plate, both were used by the expert panel to access the content validity. To access the face validity of Urdu version of LANSS expert reviewed for item 1,3,7 and 4 is 90% (n=9) reported YES. For item 2 and 5 80 % (n=10) expert were agreed. And for item 100% (n=10) reported YES. CVI reported and calculated for the relevance of 7 items of Urdu version LANSS was 0.8857 that is Excellent.

### Pilot study

10 patients from the targeted population were taken for pretesting, of which 5 participants were females (50%) and 5 participants were males (50%). Pearson correlation coefficient includes a good range (r-value = 0.69), showing that the Urdu version of LANSS is concurrently valid. Significance relationship exits in overall items of the Urdu version of LANSS and Pain (VAS) whose r -value is 0.69 and p-value is <0.05. Construct validity of Urdu version of DN4 had been analyzed through Pearson correlation and r -value = <0.06 and p-value = <0.05 shows that a negative relationship occurs between the Urdu version of LANSS and Barthel index on the third follow-up day.

#### **Target Participants:**

A sample size of 70 participants filled the 07 items translated LANSS. This is a self-reported questionnaire, so they filled the questionnaire by themselves. Along with Urdu LANSS they also participated in the filling of the visual analogue scale, and Barthel index on three different points, for the analysis of construct validity, convergent validity, and test-retest reliability of the translated tool. To assess reliability Cronbach's alpha coefficient was calculated to determine the internal consistency of Urdu version LANSS as shown in table 18. The Cronbach's alpha between the first clinical rotation day and the third follow-up day was calculated to be 0.76 which is acceptable. The Cronbach's alpha for the second follow-up day and the third follow-up showed good internal consistency reliability of DN4 was calculated to be 0.81 and the Cronbach's alpha coefficient between the second and third follow-up day was calculated to be 0.82 means having good internal consistency. To check the responsiveness of the LANSS, Paired T-test for the Urdu version of

LANSS was calculated for the first clinical rotation day, the second follow-up day, and the third follow-up day. Three pairs were established between these days including LANSS at the first clinical rotation day and LANSS at the second follow-up day with means of  $67.2\pm6.9$  and  $69.4\pm7.3$  respectively, the second pair was between LANSS at the first clinical rotation day and the third follow-up day with mean of  $67.2\pm6.9$  and  $73.2\pm7.5$  respectively, and the last pair was between LANSS on second follow up day and the third follow up day with mean of  $69.4\pm7.3$  and  $73.2\pm7.5$  with P- value <0.05 respectively.

#### **Tables**

Table 1: Frequency and Percentage of the baseline characteristics of Pretested Participants LANSS

| LANS           |                 |          |              |  |  |
|----------------|-----------------|----------|--------------|--|--|
| Variable       | Category        | LANSS    |              |  |  |
|                |                 | All      | Frequency    |  |  |
|                |                 | Subjects | (Percentage) |  |  |
|                |                 | (n=10)   |              |  |  |
| Gender         | Male            | 5        | 5(50%)       |  |  |
|                | Female          | 5        | 5(50%)       |  |  |
| Occupation     | Employed        | 6        | 6(60%)       |  |  |
|                | Unemployed      | 4        | 4(40%)       |  |  |
| Nerve Involved | Upper Extremity | 4        | 4(40%)       |  |  |
|                | Lower Extremity | 3        | 3(30%)       |  |  |
|                | Both            | 3        | 3(30%)       |  |  |
| Extremity      | Upper Extremity | 4        | 4(40%)       |  |  |
| Involved       | Lower Extremity | 3        | 3(30%)       |  |  |
|                | Both            | 3        | 3(30%)       |  |  |
|                | LANSS           |          |              |  |  |
|                | All Subjects    |          |              |  |  |
|                | (N=40)          |          |              |  |  |
| Variables      |                 | r        | Mean±SD      |  |  |
| Age (Years)    | 40              | 5        | 53.57±13.1 4 |  |  |
| Height(Meters) | 40              | 1        | 67.57±8.3    |  |  |
| Weight(kg)     | 40              | 7        | 70.82±10.8 9 |  |  |
| BMI            | 40              | 2        | 25.4±4.3     |  |  |

**Table 2: Content Validation (CVI) -LANSS** 

| Item Description Number Agreement I-CVI Interpretation |                  |       |                |  |
|--|------------------|-------|----------------|--|
| Tem Description  | Number Agreement | 1-011 | Interpretation |  |
| Item 1   | 9                | 0.9   | Agree          |  |
| Item 2   | 8                | 0.8   | Agree          |  |
| Item 3   | 9                | 0.9   | Agree          |  |
| Item 4   | 9                | 0.9   | Agree          |  |
| Item 5   | 8                | 0.8   | Agree          |  |
| Item 6   | 10               | 1     | Agree          |  |
| Item 7   | 9                | 0.9   | Agree          |  |

**Table 3: Concurrent Validity of the Pre-Tested Population of LANSS** 

| Measure    | R-Value | P value |
|------------|---------|---------|
| LANSS      | O.692   | < 0.05  |
| Pain (VAS) | 0.692   | < 0.05  |

Table 4: Frequency and Percentage of the baseline characteristics of Targeted Participants of LANSS

| Variable   | Category   | LANSS    |              |  |
|------------|------------|----------|--------------|--|
|            |            | All      | Frequency    |  |
|            |            | Subjects | (Percentage) |  |
|            |            | (n=70)   |              |  |
| Gender     | Male       | 31       | 31(44.3%)    |  |
|            | Female     | 39       | 39(55.7%)    |  |
| Occupation | Employed   | 29       | 29(41.4%)    |  |
|            | Unemployed | 41       | 41(58.6%)    |  |
| Extremity  | Upper      | 24       | 24(34.3%)    |  |
| Involved   | Extremity  |          |              |  |
|            | Lower      | 24       | 24(34.3%)    |  |
|            | Extremity  |          |              |  |
|            | Both       | 22       | 22(31.4%)    |  |
| Nerve      | Upper      | 24       | 24(34.3%)    |  |
| Involved   | Extremity  |          |              |  |
|            | Lower      | 24       | 24(34.3%)    |  |
|            | Extremity  |          |              |  |
| 1          | Both       | 22       | 22(31.4%)    |  |

Table 5: To access the reliability using Cronbach's alpha Coefficient to determine the internal consistency of the Urdu Version of LANSS

|                   | LANSS on the first clinical rotation day | LANSS on the second follow-up, day | LANSS on the third follow-up |
|-------------------|--|------------------------------------|------------------------------|
| Cronbach's        | chinear rotation day                     | Tonow up duy                       | day                          |
| alpha coefficient | 0.76                                     | 0.81                               | 0.82                         |

Table 6: Paired T-Test for responsiveness of Urdu Version of LANSS on the first clinical visit, the second follow-up day, and the third follow-up day

| Pairs  | Variables  | Mean ± SD | P value |
|--------|--|-----------|---------|
|        | total scoring of LANSS on the first clinical visit | 67.2±6.9  | <0.05   |
| Pair 1 | total scoring of LANSS on the second follow-up day | 69.4±7.3  |         |
| Doin 2 | total scoring of LANSS on the first clinical visit | 67.2±6.9  | <0.05   |
| Pair 2 | total scoring of LANSS on the third follow-up day  | 73.2±7.5  |         |
| Doin 2 | total scoring of LANSS on the second follow-up day | 69.4±7.3  | <0.05   |
| Pair 3 | total scoring of LANSS on the third follow-up day  | 73.2±7.5  |         |

#### Discussion

According to the results of the current investigation, LANSS's Urdu translation exhibits useful clinimetric qualities. When the researcher evaluated the Urdu version of LANSS scores at three-time points, all four items demonstrated moderate to strong loading on the factors acknowledged by the researcher, indicating strong internal consistency. In contrast to the research conducted by Gierthmühlen J that revealed substantial loading of the factors, all of the items of the Urdu version of LANSS represent different aspects of assessment and evaluation in neurological disability, despite the moderate connection. (12).

According to Hair et.al and Tabachnick et al. the KMO index ranges from 0 to 1, with 0.50 considered suitable for factor analysis. (23) From the results obtained for the Urdu version of LANSS, by construct validity the KMO values of 0.83 in this case the value of KMO is greater than 0.50. This means that the number of samples used in the testing or retrieval of data is sufficient or eligible for further factor analysis and it is consistent with the research done by Istiyono. (13)

In comparison to measurements of VAS and the Urdu version of LANSS, the concurrent validity was moderate. These findings suggest that the Urdu version of LANSS is reflecting more accurate judgments of neuropathic conditions. The correlation between VAS and the Urdu version of LANSS is significant, and the findings support Westenberg RF research.(14).

#### Conclusion

The results revealed that the test-retest reliability for LANSS is sustainable. The overall outcome depicts that the reliability coefficient for LANSS (Intraclass Correlation Coefficient=0.83, CI= 95%) is good.

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