

Translation and cultural adaptation of the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain scale into Arabic for use with patients with diabetes in Libya

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ABSTRACT

In Libya neuropathic pain is rarely assessed in patients with diabetes. The Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain scale is used worldwide to screen for neuropathic pain. There is no Arabic version of LANSS for use in Libya. The aim of this study was to develop an Arabic version of LANSS and to assess its validity and reliability in diabetic patients in Benghazi, Libya. LANSS was translated into Arabic by four bilingual translators and back translated to English by a university academic. Validity and reliability of the Arabic LANSS was assessed on 110 patients attending a Diabetes Centre in Benghazi. Concurrent validity was tested and compared with the Self-completed Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS). Test-retest reliability was conducted 1–2 weeks later. Internal consistency and inter-class correlation (ICC) between LANSS and S-LANSS was also tested. Internal consistency within first completion of the Arabic LANSS was acceptable (Cronbach's alpha = 0.793) and similar to the Arabic S-LANSS (0.796) and the second completion of the Arabic LANSS (0.795). ICC between the Arabic LANSS and the Arabic S-LANSS was 0.999 ($p < 0.001$). Test-retest reliability (ICC) between first and second completions of the Arabic LANSS was 0.999 ($p < 0.001$). Kappa measurement of agreement between the two Arabic LANSS completions and S-LANSS was high on all seven items (Kappa > 0.95 , $p < 0.0001$). We concluded that the Arabic version of LANSS pain scale was valid and reliable for use on Libyan diabetic patients. This study provided results suggesting that the S-LANSS could also be used on diabetic patients.

ARTICLE HISTORY

Received 15 June 2017
Accepted 20 September 2017

KEYWORDS

Pain; diabetes; painful diabetic neuropathy (PDN); leeds assessment of neuropathic pain symptoms and signs (LANSS); self-report version of the leeds assessment of neuropathic pain symptoms and signs (S-LANSS) pain scale; Libya

1. Introduction

Screening for neuropathic pain is critical for successful pain management and is dependent on valid and reliable screening tools adapted for populations from diverse ethno-cultural backgrounds [1]. Tools used to screen for the presence of neuropathic pain have been developed in English, French and German for use in European countries and the USA, and include the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) [2], the self-reported version of the LANSS (S-LANSS) [3], the Neuropathic Pain Questionnaire (NPQ) [4], the Douleur Neuropathique 4 questions (DN4) [5], painDETECT [6], ID-Pain [7] and the Standardized Evaluation of Pain (StEP) [8]. These tools rely on the patient's verbal description of the nature of their pain and may include a simple clinical examination. Screening tools need to be translated and culturally adapted if they are to be used in languages other than English, French and German.

The LANSS and S-LANSS pain scales are used globally to screen for the presence of pain of neuropathic origin because they have high sensitivity and

specificity compared with other available tools [1]. The LANSS pain scale consists of five items that document self-reported pain symptoms and two items that document the findings of a simple clinical examination conducted by the healthcare professional to assess the presence of allodynia and pin-prick threshold [2]. A score of 12 or more out of 24 is used as a cut-point to identify pain that is predominantly neuropathic in origin. The S-LANSS was designed to remove the need for clinical examination by a health care professional by modifying the two clinical examination items so that they could be undertaken by the patient themselves [3]. Thus, the S-LANSS can be sent to the patient by post or completed verbally via telephone conversation [3,9].

The sensitivity of the LANSS is 83% and specificity is 87%, with an ability to identify neuropathic pain in 85% of patients with clinically confirmed diagnosis of neuropathic pain [2]. The sensitivity and specificity of the S-LANSS is lower than LANSS (i.e. 74% and 76%, respectively) with an ability to identify neuropathic pain in 75% of patients with clinically confirmed diagnosis of neuropathic pain [3]. Specificity and

sensitivity remain stable when translated versions of the LANSS and S-LANSS are used in non-English speaking populations including Turkish [10,11], Spanish [12] and Chinese [13]. The LANSS pain scale has been translated, linguistically validated and culturally adapted for use in Turkish, Dutch, Spanish, French and Chinese populations [10,13,14]. The S-LANSS has been translated, linguistically validated and culturally adapted for use in Arabic populations [9], but there is no equivalent LANSS pain scale for use in Arabic populations.

Libya is an Arab country in the Middle East and North Africa (MENA) region with a population of approximately 6 million. Health care provision in Libya is similar to other MENA countries with limited services for the management of diabetes and chronic pain [15]. The need to develop improved services for the management of pain for patients with diabetes has been recognised in policies (e.g. the Diabetes Care Plan), but implementation has been hindered due to war. An Arabic S-LANSS has been developed and validated for use for the general population in Libya [9], and was used to estimate the point prevalence of neuropathic pain in a sample of adults experiencing chronic pain [16]. However, the Arabic S-LANSS has not been validated for use in populations of adults with specific disease states.

In 2000, it was estimated that 88,000 people were diagnosed with diabetes in Libya and that this figure would rise to 245,000 people by 2030 [17]. In 2015, 354,000 people in Libya were diagnosed with diabetes indicating a far greater burden than originally believed [18]. Painful diabetic neuropathy is a common complication of diabetes affecting up to a third of patients [19,20] but there are no up-to-date data on the prevalence, risk factors and treatment of painful diabetic neuropathy in Libya. There is a need for a culturally adapted screening tool to aid health care professionals screen for the presence of neuropathic pain associated with diabetes. The aim of this study was to develop an Arabic version of the LANSS pain scale and to assess its linguistic validity and reliability on patients with diabetes in Benghazi, Libya. In addition, anthropometric data, clinical profiles, co-morbidities and complications were collected to better describe the sample.

2. Methods

2.1. Translation of the LANSS to Arabic

This study involved translation of the LANSS from English to Arabic. Participants with diabetes completed the Arabic LANSS on two occasions with a week interval, and also completed the Arabic S-LANSS on one occasion. Data gathered was used to test the validity, reliability and cultural

appropriateness for use in Libya. Permission to conduct the study was obtained from the Benghazi Diabetes Centre and ethics approval was obtained from the Research Ethics Committee at Leeds Beckett University.

The translation process followed the Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcome Measures [21] using the following steps:

- (1) Preparation: Four bilingual translators who were fluent in Arabic and English were selected. Three translators were clinicians and one translator was a university academic.
- (2) Forward translation: the LANSS was given to all translators to translate into Arabic.
- (3) Reconciliation: The four translated documents were shared between all translators and discrepancies, ambiguities and issues arising were discussed and resolved by consensus. A final draft Arabic version of the LANSS was produced.
- (4) Backward translation and review: The final draft Arabic version of the LANSS was translated back into English by a translator who had not been involved in forward translation and who was blind to the original English version of the LANSS.
- (5) Harmonization, cognitive debriefing and reviewing of results: The back-translated English version of the LANSS was compared with the original LANSS and discrepancies, ambiguities and typographic and/or grammatical errors discussed within the group and a final draft of the Arabic version.
- (6) Proof reading and final report: The authenticity of the translation was agreed by consensus and a final version of the Arabic LANSS produced.

It is worth noting that the original developers of the LANSS were not involved in initial translation as they were not Arabic speakers. However, the back translation was compared to the original by members of the team who originally developed the Arabic version of the S-LANSS.

2.2. Testing reliability and linguistic validity of the Arabic S-LANSS

The sample size needed to detect a statistically significant correlation between the scores of the LANSS and the S-LANSS was calculated based on the assumption that a probability is 95 percent that the study will detect a relationship between Score of the S-LANSS and the Score of the LANSS at a two-sided 0.05 significance level. This calculation suggested that 100 participants would be required so a target of 110 participants was set to account for 10% attrition. It was

also estimated that this sample size would be sufficient for calculating the internal consistency of the LANSS items using Cronbach's alpha.

2.3. Recruitment and selection of sample

Eligibility criteria for inclusion in the study were adults (≥ 18 years) who had a formal diagnosis of diabetes which has been present for at least five years. Individuals were excluded if they were: a hospital in-patient; had pre-existing comorbidities such as cancer, shingles or other neuropathic pain entity that predated diabetes or can mimic or cause a neuropathic pain that is not arising as a result of diabetes; were pregnant as diabetes may be of gestational type; had recently experienced physical trauma that may have contributed to neuropathic pain; and had trauma or dermatological diseases of the skin as this could affect skin sensitivity (e.g. wound, psoriasis and eczema).

2.4. Study procedures

The study was advertised by posters and by word of mouth at the Benghazi Diabetes Centre. Interested volunteers received a participant information sheet and a self-screening eligibility form and were asked to contact the Principal Investigator (SG) no sooner than 48 h if they wished to volunteer to participate in the study, which consisted of two visits to the clinic.

During study visit 1, participants were briefed about the study, screened for eligibility and enrolled onto the study by signing a consent form. Demographic data, such as age, weight and height, were also collected to describe the sample. Participants completed the Arabic LANSS and the Principal Investigator undertook the clinical examination for tactile allodynia and pinprick threshold by touching painful and adjacent non-painful areas with a cotton wisp and a syringe needle, respectively. Participants then completed the Arabic S-LANSS. A nurse assisted participants with reading difficulties. Participants returned for study visit 2 after 7–14 d and completed the Arabic LANSS questionnaire. Participants were also required to report other symptoms and complications associated with diabetes.

2.5. Data analysis

The data were analysed using SPSS 22. Concurrent validity was tested by comparing Arabic LANSS scores from study visit 1 and 2 with the Arabic S-LANSS score. The inter-class correlation coefficient (ICC) was calculated for total score of the two questionnaires (LANSS visit 1 and 2). Test-retest reliability of the Arabic LANSS was tested by calculating the ICC of all items and comparing the total score for the two study

visits. Cronbach's alpha was calculated for the Arabic LANSS using data gathered from the two study visits.

It is worth noting that the inter-class correlation was used to determine agreement between total scores of the Arabic S-LANSS versus the Arabic LANSS in visit 1 and also between the two visits of the Arabic LANSS because the possible total score, which is based on a numerical value given to Yes or No answers to the questions, ranged from 0 to 24 and therefore is treated as continuous. However, Cohen Kappa was used to check the agreement between the different items as the answers to these questions are binomial (Yes or No).

3. Results

3.1. Translation of the LANSS to Arabic

There were no major issues arising during the translation process. The final version of the Arabic LANSS is presented in [Figure 1](#).

3.2. Reliability and linguistic validity of The Arabic LANSS

One hundred and ten participants enrolled and all completed the study (age = 19–82 years, Body Mass Index = 18.81–40.74 kgm², 55 females). All participants reported that they understood questions in the Arabic LANSS and Arabic S-LANSS and there were no instances of participants raising issues about ambiguous words. Questions from the LANSS and the S-LANSS were read verbatim to participants who had difficulties with reading and/or writing ([Table 1](#).) Data from one male participant were removed from analysis because they disclosed at the end of the study that they were diagnosed with diabetes within five years but did not disclose this at screening because he wanted to take part in the study. Data were missing for height and for weight for four male and one female and plasma glucose data for five males and one female. These were processed as missing data in subsequent analysis.

Anthropometric and demographic data are presented in [Table 1](#). Mean \pm SD plasma glucose concentration was 158.38 \pm 57.42 mg/dl ($n = 103$ participants). Mean \pm SD duration of diabetes was 15.28 \pm 10.06 years ($n = 109$) and females had experienced diabetes for a longer duration than males. This difference did not appear to be related to age as there were no statistically significant differences in age between female and male participants ($p > 0.05$). Twenty-eight (51.9%) males reported that they were smokers (mean \pm SD duration = 11.41 \pm 13.34 years), but none of the females reported being a smoker. Twenty-nine males (53.7%) reported that they were employed compared with 23 females (41.8%,

مقياس ألم لانس
تقييم ليزر للأعراض والعلامات ذات المنشأ العصبي

الرقم:..... التاريخ:.....

الأم بإمكانه المساعدة في تحديد ما إذا كانت الأوصاف التي تتل إشارات الألم تعمل بصورة طبيعية أم لا. من برفة ذلك في حالة وجود طرق مختلفة للعلاج قد تحتاجها للتحكم في الألم

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1) ألم الجذ:

إحساس الإحساس للسن الخفيف بقلعة من اللظن على المنطقة الغير مؤلمة أولاً ثم على المنطقة المؤلمة. إذا كان الإحساس طبيعي في المنطقة الغير مؤلمة والإحساس بالألم أو الشعور بالفتيان أو وخز في المنطقة المؤلمة، إذا ألم الجذ موجودة.

(a) لا- الإحساس الإحساس طبيعي في كلا المنطقتين (0)

(b) نعم- أشعر بهذا الإحساس كثيراً (5)

2) تغيير عتبة الإحساس بالوخز

فترة حمل الرخز لتحديد بمقدرة الإحساسية للوخز بدرجة 23 مقياس جوج، زرقاء اللون مثبتة على حقة مقياس 2 مل، تجرب على المكان المؤلم ثم على المكان غير المؤلم على التوالي.

إذا نتج عنه إحساس بآلم حاد في المكان الغير مؤلم وإحساس غريب بعدم الألم أو بسيط في المكان المؤلم (ارتفاع عتبة الألم) أو ألم شديد جداً (انخفاض عتبة الألم) ذلك يؤكد اضطراب في عتبة الألم.

(a) لا- الإحساس متساوي في كلا المنطقتين (0)

(b) نعم- اضطراب عتبة الإحساس بالألم في المنطقة المؤلمة (3)

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حساب المعدل :-

(إجمالي الأرقام التي بين الأقواس التي تمثل وصف الإحساس بالألم ونتائج التفرعات للحصول على المعدل النهائي).

المعدل النهائي (أقصى درجة 24)

إذا كان المعدل أقل من 12 ، ميكانيكية الألم العصبي غير مرجحة أن تكون سبب في ألم المريض

إذا كان المعدل أكثر من 12 ، من المرجح أن ميكانيكية الألم العصبي هي المسببة في ألم المريض

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Figure 1. The Final version of the Arabic Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain scale.

Table 1. Mean + SD or tallies of anthropometric and demographic data of participants.

Characteristic	Men (n = 54)	Women (n = 55)	All sample (n = 109)	P value ^a
Age (years)	48.09 ± 14.84	51.62 ± 14.00	49.87 ± 14.47	0.21
BMI (kg/m ²)	28.43 ± 4.87	29.14 ± 4.89	28.80 ± 4.87	0.46
Plasma glucose (mg/dl)	154.08 ± 59.20	162.28 ± 56.02	158.38 ± 57.42	0.47
Duration of diabetes (years)	12.56 ± 7.12	17.95 ± 11.74	15.28 ± 10.06	0.05
Smoking (%)	n = 28 (51.9%)	n = 0 (0%)	25.7%	0.00
Duration of smoking (years)	11.41 ± 13.34		11.41 ± 13.34 ^b	0.00
Employment (%)	n = 29 (53.7%)	n = 23 (41.8%)	n = 52 (47.7%)	0.21
Education (%)				
• Cannot read or write	n = 9 (16.7%)	n = 15 (27.3%)	n = 24 (22.0%)	0.18
• Can read and write	n = 7 (13.0%)	n = 8 (14.5%)	n = 15 (13.8%)	0.82
• Primary	n = 8 (14.8%)	n = 9 (16.4%)	n = 17 (15.6%)	0.81
• Secondary	n = 17 (31.5%)	n = 10 (18.2%)	n = 27 (24.8%)	0.11
• University or above	n = 13 (24.1%)	n = 13 (23.6%)	n = 26 (23.9%)	0.95
Marital status (%)				
• Married (no children)	n = 6 (11.1%)	n = 0 (0%)	n = 6 (5.5%)	0.01
• Married (with children)	n = 40 (74.1%)	n = 51 (92.7%)	n = 91 (83.5%)	0.00
• Unmarried	n = 8 (14.8%)	n = 4 (7.3%)	n = 12 (11.0%)	0.00

^aDifferences between mean ± SD of men and women were tested by unpaired t-test, while differences between proportions of males and females in other parameters were tested by Z-test.

^bNone of the women were smokers, so there is no mean or standard deviation for this group. In all sample these figures are only for males.

$p = 0.21$). Forty-five participants scored ≥ 12 points on the Arabic LANSS at study visit 1 and 45 participants scored ≥ 12 points on study visit 2. Forty-five participants scored ≥ 12 points on the Arabic S-LANSS at study visit 1. Hence, point prevalence of peripheral diabetic neuropathy was calculated as 41.3% (95% Confidence Intervals = 32.55–50.7%).

Participants in the sample presented with a variety of complications associated with diabetes including eye problems (e.g. cataract $n = 28$, 25.7%), erectile dysfunction ($n = 14$, 12.8%), joint stiffness ($n = 9$, 8.3%). Participants in the sample presented with a variety of comorbidities such as hypertension

($n = 31$, 28.4%), heart diseases ($n = 20$, 18.3%), thyroid gland disorders ($n = 17$, 15.6%), arthritis ($n = 6$, 5.5%), asthma ($n = 2$), kidney disease ($n = 1$), hepatitis ($n = 1$) and hyperlipidaemia ($n = 1$). Only eight (7.3%) participants reported that they had been diagnosed with peripheral diabetic neuropathy.

3.3. Internal consistency

Cronbach's alpha values suggested acceptable internal consistency for Arabic LANSS scores at study visit 1 (0.793) and this was similar to that for Arabic S-LANSS scores (0.796). Cronbach's alpha suggested

Table 2. Kappa measurement of agreement between Arabic LANSS and Arabic S-LANSS scores at study visit one and for Arabic LANSS between study visit 1 and 2.

	Arabic LANSS (visit 1) vs Arabic S-LANSS (visit 1)		Arabic LANSS visit 1 vs Arabic LANSS visit 2	
	Kappa	P value	Kappa	P value
	Item 1	0.98	<0.01	1
Item 2	1	<0.001	1	<0.001
Item 3	1	<0.001	1	<0.001
Item 4	0.98	<0.01	0.98	<0.01
Item 5	0.95	<0.01	1	<0.001
Item 6	1	<0.001	1	<0.001
Item 7	0.97	<0.01	1	<0.001

acceptable internal consistency for Arabic LANSS scores between study visit 1 and 2 (0.795).

3.4. Concurrent validity

Inter-class correlation values between Arabic LANSS total scores and Arabic S-LANSS total scores at study visit 1 suggested acceptable concurrent validity. Kappa measurement of agreement between Arabic LANSS and S-LANSS scores at study visit 1 was very high for all seven items (Table 2).

3.5. Test-retest reliability

Inter-class correlation between Arabic LANSS total scores at study visit 1 and 2 was 0.999 ($p < 0.001$) suggesting acceptable test-retest reliability. Kappa measurement of agreement was high for all items of the Arabic LANSS between studies visit 1 and 2 (Table 2).

4. Discussion

To our knowledge, this is the first report of the translation and cultural adaptation of the LANSS pain scale into Arabic. We used an Arabic S-LANSS pain scale that had been culturally adapted for use in Libya [9] to test concurrent validity of the Arabic LANSS pain scale. The Arabic LANSS had high test-retest reliability and data suggested that it was linguistically valid and culturally suitable for use on people with diabetes in Benghazi, Libya. It was easy to complete, suggesting that translated versions of the LANSS pain scale have clinical utility in ethno-culturally diverse populations.

We decided to translate the LANSS pain scale because the sensitivities and specificities of different languages of the LANSS are higher than 80% [1]. The Turkish LANSS has a sensitivity of 89.9% and a specificity 94.2%, and a positive predictive value of 93.6% and a negative predictive value of 90.7% [10]. The Spanish LANSS has good reliability with Cronbach and Guttman split-half coefficients between 0.68 and 0.71 and a kappa coefficient for inter-rater agreement of 0.70 and intra-class correlation coefficients between 0.77 and 0.92. Specificity is 89.4% and positive predictive value is 91.1%. Validity is good

with a kappa coefficient of 0.70 (CI 95% 0.59–0.81; $p < 0.0001$) and area under the curve 0.929 ($p < 0.0001$) [12]. Cultural validation in China was highly reliable with Cronbach's alpha coefficients and Guttman half coefficients for internal consistency being 0.824 and 0.842, respectively. It has good face validity and high content validity with sensitivity being 80.0% and specificity 97.1%, and a positive predictive value of 96.9% and negative predictive value of 82.9% [13]. Moreover, the Neuropathic Pain Questionnaire (NPQ) has the lowest reported accuracy of other available tools and the DN4 may not preserve its diagnostic accuracy in specific patient populations such as acute postoperative pain patients. PainDETECT had lower sensitivity and specificity when tested on other pain groups than the originally validated and the ID-Pain is relatively sensitive but not specific in specific pain groups such as patients with breast cancer. The Standardized Evaluation of Pain (StEP) is copyrighted and has only been validated in a lower back pain group [1].

Our study is the first to provide initial data related to the point prevalence of painful diabetic neuropathy in Libya. We found that 41.3% of participants, in this small sample, diagnosed with diabetes that has persisted for at least five years presented with painful diabetic neuropathy. This estimate is of similar magnitude to previous reports on larger samples from populations in the Middle East. For example, Jambart et al. [22] estimated the point prevalence of painful diabetic neuropathy to be 53.7% in a population of 4097 from five different MENA countries. However, our estimate is preliminary and based on a study designed to translate the LANSS into Arabic. The small sample size of participants recruited from a single clinic from one city means that the estimate should be treated with caution. A large multi-site epidemiological study is needed. Our study found that plasma glucose levels were higher than normal ranges for patients with diabetes, especially in patients with possible painful diabetic neuropathy. This might support the theory that painful diabetic neuropathy is more common in patients with poorly controlled diabetes [23]. Our finding that none of the female participants reported being smokers is consistent with data from the Tobacco Atlas that only 0.9% of females aged >15 years in Libya are daily smokers [24].

4.1. Strengths and limitation of the study

The findings of our study have clinical implications, especially for healthcare professionals working in diabetes clinics. Small modifications of service delivery in diabetes clinics could improve the detection and management of painful diabetic neuropathy in patients with diabetes. Clinicians should be mindful of patients reporting pain and/or sensory

disturbances in the previous six months. In Libya and the MENA region the Arabic LANSS or the S-LANSS, which can be completed within minutes can be used in service delivery to detect the presence of painful diabetic neuropathy. This information can then be used to inform health care professionals about the most appropriate pharmacological strategy to adopt.

However, our findings on the initial prevalence of neuropathic pain should be approached with caution as the sample is not very representative and is very small. In addition, the intention of the study was to test the validity and reliability of the Arabic LANSS and not to provide epidemiological figures. Another major limitation of this study is that there was no gold standard method to test the sensitivity and specificity of the Arabic LANSS such as detailed case history, clinical examination and further investigations if needed; this was not feasible as the time-frame for the study and resources were limited. Moreover, the testing of concurrent validity of the LANSS by comparison with the similar S-LANSS completed at the same time is a drawback.

4.2. Conclusion

The Arabic LANSS pain scale developed in this study was valid and reliable for use in Libya for people diagnosed with diabetes. This study provided data suggesting that the S-LANSS could also be used in this population. However, the use of the S-LANSS in a postal survey is limited to patients with reading difficulties. We plan to use the Arabic LANSS or S-LANSS in an epidemiological study to estimate the point prevalence of painful diabetic neuropathy in Libya.

Acknowledgements

The authors wish to thank all the translators who helped in translation and back translation of the Leeds Assessment of Neuropathic Pain Symptoms and Signs (LANSS).

ACCESSING RESEARCH MATERIALS: Underlying research materials related to our paper (for example data, samples or models) can be accessed by contacting Osama Tashani or Sabri Garoushi.

Disclosure statement

No potential conflict of interest was reported by the authors.

Funding

This study was funded by a Libyan Higher Education Authority PhD bursary

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