Original Article

Validation of Complete Hindi Version of Douleur Neuropathique 4 Questionnaire for Assessment of Neuropathic Pain

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ABSTRACT

Objectives: The Douleur Neuropathique 4 (DN4) questionnaire is a widely used tool for the diagnosis of neuropathic pain (NP). The aim was to validate the Complete Hindi version of DN4 (CH-DN4) questionnaire.

Materials and Methods: A systematic translation process was used to translate the original English DN4 into Hindi. The Hindi version was validated among patients appearing in the pain clinic of a tertiary hospital in the capital of Delhi by two different raters. We assessed the internal consistency, test–retest reliability, and inter-rater agreement, validity, sensitivity, specificity, positive and negative predictive values, and area under the curve (AUC).

Results: A total of 285 participants, out of which 153 had NP and 132 had non NP (NNP) were included in the study. The results showed our CH-DN4 to have good diagnostic accuracy, a score of ≥ 3.5 was found to be the best cut–off for the diagnosis of NP, with a sensitivity of 0.78, specificity of 0.76, a positive predictive value of 78.5%, and a negative predictive value of 74.5%. Cronbach's α was 0.82 (95% confidence interval: 0.80–0.84), and interclass correlation coefficients was 0.95. The AUC was >0.8 indicating excellent discrimination between NP and NNP.

Conclusion: The CH-DN4 questionnaire has been found to be a reliable and valid screening tool with an excellent power to discriminate between NP and NNP.

Keywords: Complete Hindi Version douleur neuropathique 4, Neuropathic pain, Reliability, Sensitivity, Specificity

INTRODUCTION

Neuropathic pain (NP) is defined as pain that is caused by lesions or disease of the somatosensory system.[1] The prevalence of NP is estimated to be 3.3%–11.8% of the general population.[2] Proper identification of this type of pain is of paramount importance as the response to different analgesics is dependent on the nature of painful stimulus and its underlying mechanism.

Various questionnaires that have been utilized in pain practice to differentiate NP pain from non-NP (NNP) but each one of them have their own merits and demerits and upper edge and limitations.[3-8] The Douleur Neuropathique-4 (DN4) questionnaire, introduced by Bouhassira *et al.*[3] in 2005, is one of the simple and most widely used questionnaire for clinical practice and research use. It is a clinician administered questionnaire consisting of a total of 10 items grouped in four sections. The first seven items are related to the quality of

pain (burning, painful cold, and electric shocks) are based on an interview with the patient, and three items based on the clinical examination are related to the presence or absence of touch hypoesthesia, pin-prick hypoesthesia, and tactile allodynia.

The DN4 questionnaire has been validated in various languages such as Farsi, Spanish, Arabic, Dutch, Greek, Turkish, Thai, and Korean language.[9-16] The original French version of DN4 questionnaire has very good sensitivity (83%) and specificity (90%) for the identification of chronic NP as a consequence of a lesion or disease of the nervous system (either peripheral or central).[3]

Various researchers, including Bouhassira *et al.*[3] and Gudala *et al.*,[17] have validated an interview version of the DN4 or Short form of DN4 including only 7 self-completing items on various NeP symptoms and not the whole 10 items. The reason for pursuing the short form and not the complete DN4 was the ease and lack of manpower and time by both the studies. As far as the Hindi language is concerned, the latter study by Gudala *et al.* in 2017 studied the validity and reliability of short form of Hindi version of DN4 which consisted of only 7 interview-based items and did not include the clinical examination-based items.[17] Therefore, no data are available in context to the validation of complete Hindi version of DN4. Hence, the present study was designed as to assess the validity and reliability of the CH-DN4 questionnaire (CH-DN4) for differential diagnosis of chronic pain of neuropathic or nonneuropathic component.

MATERIALS AND METHODS

The present, cross-sectional, observational study was undertaken following the approval from the Institutional Ethics Committee (Human) and was conducted between November 2016 and April 2018. Written informed consent was obtained from each participant.

Patients with established diagnosis of either NP or NNP who are ≥18 years of age with pain duration of at least 3 months with pain intensity of ≥4 on 10 cm on the Visual Analog Scale (VAS).

We designed the validation process of DN4 into Hindi according to the traditional standard recommendations for cross-cultural adaptation through four separate steps. In the first step, we had taken the help of an expert translator, for translating the English version of DN4 questionnaire into Hindi. During translation, there was some disagreement among us on two Hindi synonyms of "tingling" and "numbness." However, the final result was approved following changes in two of the above synonyms. In the 2nd phase, retranslation of that Hindi version was retranslated back to English again by taking the help of an expert translator. In the third step, the semantic and literal assessment between translated and retranslated

versions was performed. In the last step, practicability and interpretation difficulties of the final Hindi version of DN4 questionnaire were assessed on pilot group of 10 patients of NP and NNP.

Patients coming to Pain clinic were assessed using this CH-DN4 Questionnaire. For each patient, the detailed DN4 questionnaire was filled up by two doctors separately. Thus, each patient had two forms of the CH-of questionnaire filled up. The S-DN4, consisting of seven items which are interview based i.e., if the pain is burning, painful cold, electric shocks, tingling, pins and needles, numbness, and itching. Rest three are based on the clinical examination by the expert. The positive responses were scored as 1 and negative ones as 0. A total sum of these items provided the summary score of the S-DN4 [Annexure II]. In addition, the Visual Analog Pain Score (VAS) was assessed on a visual scale from 0 to 10 with 0 being none and 10 being unbearable. The CH-DN4 was preferable filled by both the raters on the same day; however, in exceptional situation not beyond day 3. The CH-DN4 questionnaire of these 280 patients was properly secured and maintained in file. After completion of these two forms each of the 285 patients, the data were analyzed statistically.

Sample size calculation

The sample size was calculated on the basis of inter-rate agreement using Intra-class correlation coefficient (ICC) between two observers and also using the estimation of sensitivity and specificity. The previous study by Madani *et al.*[9] showed the inter-rater agreement (ICC) for DN4 score between the two observers was around to 0.92. Considering this as minimum acceptable level of inter-rater agreement and expecting the inter-rater agreement of ICC = 0.94 in our study with 80% power and 5% level of significance, we required 280 patients taking two-observers. Madani *et al.*[9] showed the sensitivity was 90% and the specificity was 95% with a ratio of NP to NNP patients. Expecting the 90% estimate of sensitivity and specificity in our study, we required 278 participants with 95% confidence level and considering 50% of suspecting patients had NP. On the basis of the above criteria, we needed at least 280 participants. Hence, finally, we included 285 patients.

Statistical analysis

Statistical analysis was performed using the IBM SPSS statistics for windows, version 20.0. Armonk, NY. To describe continuous and qualitative variables, mean (standard deviation) and frequency (percentage) were used, respectively.

The internal consistency of the questionnaire was done using the Cronbach's alpha coefficient, which was calculated within each of four domains and for the whole questionnaire. Furthermore, interclass coefficient (ICC) and the 95% confidence interval (CI) for the point estimations were based

on test and retest data to detect for reproducibility in the understanding of the items of the instrument.

Receiver operating characteristics (ROC) analysis was performed for assessing the accuracy of DN4 scores in the discrimination of NP and NNP. For this purpose, first condition was defined as the binary discriminated outcomes, "neuropathic versus NNP" (total number of patients = 285). Thereafter, the best cutoff point was reported with respect to corresponding diagnostic value of each DN4 score and calculated Youden index corresponding to each cutoff value. Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and the 95% CI of each diagnostic item were calculated for the cutoff value.

RESULTS

A total of 285 patients with chronic pain were assessed using this CH-DN4 questionnaire. Out of 285 patients, 153 patients had NP and 132 had NNP. The various clinical diagnosis and the demographic characteristics of the patients are shown in Table 1.

The average duration of chronic pain was 11 months for 285 patients. Duration of pain was higher in patients with NP. Majority of the patients with the diagnosis of NP had VAS score higher than that of patients with NNP. The mean VAS score of all the patients was 6.0 [Table 2].

Table 1: Distribution of common causes of neuropathic pain and non-neuropathic pain in the study patients.

Neuropathic pain	Non-neuropathic pain
PHN (*n=73*)	Osteoarthritis (*n=86*)
Polyneuropathy (*n=28*)	Low back pain (*n=34*)
Phantom limb pain (*n=18*)	Spondylolisthesis (*n=12*)
Trigeminal neuralgia (*n=24*)	
Post-surgical pain syndrome (*n=4*)	
Multiple sclerosis (*n=6*)	
PHN: Post Herpetic Neuralgia	

Table 2: Demographic profile.

Variable	Total	NP (*n=153*)	NNP (*n=132*)
Age (years)	51.10±12.21	54.10±12.18	48±10.34
Sex (females) (%)	157 (55)	71 (46)	86 (65)
Duration of pain (months)	11.53	15.79	10.32
Baseline VAS score of pain	6.0	6.7	5.6
NP: Neuropathic, NNP: Nonneuropathic, VAS: Visual Analogue Pain Scale			

Analysis of psychometric properties of the Hindi version of Douleur neuropathique 4 questionnaire

Internal consistency

Internal consistency of the questionnaire was estimated using Cronbach's α. A value of Cronbach's α ≥0.7 was considered sufficient. Table 3 summarizes the internal consistency using Cronbach's α for the Hindi version of the DN4 questionnaire. The data support the reliability of the H-DN4 in terms of internal consistency as measured by Cronbach's α coefficient, as it was found to be >0.7 by both the raters and indicates acceptable to good internal consistency [Table 4].

Internal consistency (Cronbach's-α coefficient) after removing each item

The Cronbach's-α coefficient ranged from 0.80 to 0.84 when a single item was deleted. No much difference was observed in the internal consistency as measured by Cronbach's α coefficient by dropping any single item. This justifies the contribution of each item of the CH-DN4 questionnaire. As the Cronbach's-α coefficient remained ≥ 0.8 at all points, this indicates a good internal consistency [Table 3].

Table 3: Internal consistency of complete Hindi version of Douleur neuropathique 4, if single item is deleted.

Items	Cronbach's α coefficient	Cronbach's α coefficient (if single item is deleted)
Burning	0.82	0.806
Painful cold		0.819
Electric shocks		0.810
Tingling		0.822
Pins and needles		0.815
Numbness		0.837
Itching		0.825
Touch hypoesthesia		0.804
Pricking hypoesthesia		0.804
Brushing		0.808
NP: Neuropathic, NNP: Nonneuropathic		

Table 4: Internal consistency (Cronbach's α coefficient) of complete hindi version of Douleur neuropathique 4.

ROCs (Reciever operating chracteristics)	Rater 1	Rater 2
Overall Cronbach's alpha coefficient) in all patients	0.831	0.822
Patients with NP (153)	0.785	0.772
Patients with NNP (132)	0.704	0.660
NP: Neuropathic, NNP: Nonneuropathic		

Inter-rater agreement

Inter-rater agreement was determined by using Cohen's Kappa coefficient and intra-class correlation coefficient. The ICC > 0.8 was considered to have excellent reliability. Calculation of the kappa coefficients supported the inter-rater agreement regarding diagnostic classification. Inter-rater reliability using Cohen's kappa coefficients ranges from 0.65 and 0.84 and questionnaire stability using intra-class correlation coefficients ranges from 0.85 to 0.95. The ICC was observed to be > 0.8 in patients with NP and NNP, whereas the overall ICC was observed to be 0.9. This indicates excellent reliability of the CH-DN4 [Table 5].

Validity

Table 6 compares the results of various scale such as the Youden Index, sensitivity, specificity, PPV, and NPV and area under curve (AUC) between Rater 1 and Rater 2. Both the sensitivity and specificity for the CH-DN4 questionnaire between the Rater 1 and Rater 2 were found to be comparable. The PPV and NPV were also found to be comparable between both the raters.

ROC curve analysis was performed to determine the cutoff value of the questionnaire score providing the best values of sensitivity and specificity for NP diagnosis. The graph plotting the cutoff point optimizing the sensitivity and specificity values show a cutoff point ≥3.5 as the most appropriate value discriminating between NP and NNP in the total sample by both the raters. At the cutoff point ≥3.5, the sensitivity and specificity were 0.80 and 0.78, respectively, by rater 1, and the sensitivity and specificity of 0.77 and 0.75, respectively by the rater 2. The sensitivity and specificity were found to be comparable by both the raters, i.e., 0.80 versus 0.77 and 0.77 versus 0.75, respectively, at the cutoff point ≥3.5.

The AUC was calculated from the ROC curve. The AUC of 0.5 indicates "no discrimination," 0.70–0.79 indicates "acceptable discrimination," 0.80–089 indicates "excellent discrimination," and > 0.90 indicates "outstanding discrimination." The AUC was found to be 0.821 (0.77–0.87) and 0.829 (0.77–0.87) by Rater 1 and Rater 2, respectively, and it was found to be statistically significant. In addition, the AUC was found to be comparable by both the raters. The AUC > 0.8 in the present study indicates excellent discrimination between NP and NNP [Table 7].

DISCUSSION

In the present study, the sensitivity and specificity of the CH-DN4 were observed to be 0.78 and 0.76, respectively. Similarly, the PPV and NPV were 0.785 and 0.745, respectively. These findings suggest the transcultural validity of DN-4 questionnaire.

The original DN-4 questionnaire was first validated in the French language and was used for the identification of chronic NP.[3] The DN4 is a clinician administered questionnaire consisting of 10 items. Seven items related to pain quality are based on an interview with the patient and three items based on clinical examination related to the presence or absence of touch or pin-prick hypoesthesia and tactile allodynia. So far, DN4 questionnaire has been cross culturally adapted and validated in various languages such as Farsi,[9] Spanish[10] Arabic,[11] Dutch,[12] Greek,[13] Turkish,[14] and Thai language.[15] All these studies have demonstrated that these translated versions of DN-4 were to be reliable and valid screening tools.

Our findings support the reliability of CH-DN4 in terms of internal consistency and inter-rater reliability as measured by Cronbach's alpha coefficient and Cohen's Kappa coefficient, respectively. The Cronbach's alpha coefficient in the present study was 0.82, and this finding is in concordance to Spanish version[10] (0.71), Korean version[16] (0.81), Arabic version[11]

Table 5: Inter-rater agreement of the complete Hindi version of Douleur neuropathique 4 questionnaire.

	Inter-rate agreement			
	Rater 1	Rater 2	ICC (95% CI)	Kappa (95% CI)
Total sample (*n*=285)	4.28±3.05	4.24±2.96	0.95 (0.94-0.96)	0.82 (0.79-0.85)
NP (*n*=153)	5.86±2.82	5.82±2.77	0.96 (0.95-0.97)	0.84 (0.79-0.89)
NNP (*n*=132)	2.45±2.15	2.41±1.96	0.85 (0.79-0.89)	0.65 (0.58-0.72)

Coefficients for the entire questionnaire (10 items) †*P*>0.05 between raters (Friedman's paired test), ‡*P*<0.001 (*P* for intra-class correlation coefficient), §Kappa using a cutoff value > 4 patients. NP: Neuropathic pain, NNP: Nonneuropathic pain (somatic), ICC: Intra-class correlation coefficient, 95% CI: 95% confidence interval.
†Friedman, Milton (December 1937). "The use of ranks to avoid the assumption of normality implicit in the analysis of variance". Journal of the American Statistical Association. 32 (200): 675–701. doi:10.1080/01621459.1937.1050352
‡Donner A, Koval JJ (March 1980). "The estimation of intraclass correlation in the analysis of family data". Biometrics. 36 (1): 19-25. doi:10.2307/2530491. JSTOR 2530491.
§Cohen, Jacob. 1960. "A Coefficient of Agreement for Nominal Scales." Educational and Psychological Measurement 20 (1): 37-46. doi:10.1177/001316446002000104.

Table 6: Comparison of the Youden Index, sensitivity, specificity, positive predictive value, negative predictive value, area under curve properties of validity for differential diagnosis of neuropathic or nonneuropathic for cutoff value≥4.

ROCs (Reciever Operating Chracteristics)	Rater 1	Rater2
Youden index	0.56	0.50
Sensitivity	0.79 (0.73- 0.85)	0.76 (0.74- 0.78)
Specificity	0.77 (0.71- 0.83)	0.74 (0.70- 0.78)
PPV	0.80 (0.75- 0.85)	0.77 (0.72- 0.82)
NPV	0.76 (0.70- 0.82)	0.73 (0.70- 0.76)
AUC	0.82 (0.76- 0.82)	0.82 (0.78- 0.87)

[†]$P<0.001$ (*P* in receiver operating characteristics curve analysis); Classification for a cutoff value ≥4 patients (McNemar's test), [‡]$P<0.001$ (*P* value for Cohen's kappa of agreement between reference diagnosis and H-DN4 classification for a cut off value ≥4 patients. Youden index = Sensitivity + Specificity - 1, 95% confidence interval in brackets. NP: Neuropathic; NNP: Non-neuropathic; PPV: Positive predictive value; NPV: Negative predictive value; AUC: Area under curve (Receiver operating characteristics curve analysis)
[†]McNemar, Quinn (June 18, 1947). "Note on the sampling error of the difference between correlated proportions or percentages". Psychometrika. 12 (2): 153-157. doi:10.1007/BF02295996. PMID 20254758
[‡]Cohen, Jacob. 1960. "A Coefficient of Agreement for Nominal Scales." Educational and Psychological Measurement 20 (1): 37-46. doi:10.1177/001316446002000104.

Table 7: Area under curve as calculated from receiver operating characteristics curve.

ROCs (Reciever Operating Chracteristics)	Rater 1	Rater 2
AUC	0.821 (0.77- 0.87)	0.829 (0.77- 0.87)
P	0.001	0.001

AUC: Area under curve (from receiver-operating characteristics curve)

(0.67; 95% CI: 0.59–0.75), and Persian version[9] (0.85). The internal consistency was not assessed for the French and Dutch version of DN4.[3,12]

Gudala *et al.* evaluated the Short form or Mini Hindi version of DN4 for the assessment of NP. They involved 160 patients with chronic pain, 80 each with neuropathic or NNP.[17] Their Hindi version of the S-DN4 has good internal consistency and test-retest reliability. However, they evaluated only the seven interview-based items of DN4, they did not evaluate the clinical examination-based rest three items of the DN-4 questionnaire which are equally important in the assessment of NP and thus vital for the diagnosis of NP.

In contrast to our study results, the sensitivity and specificity of the Arabic version[11] and Korean version[16] were found to be higher, i.e., 88.31/74.4 and 87/94, respectively, both

at the cutoff ≥4. The reason for this higher sensitivity and specificity could be attributed to the small sample sizes, i.e., 142 with Arabic version[11] and 83 with Korean version.[16] Similar to our results, the study validating the Spanish version[10] of DN4 in 164 patients showed a sensitivity and specificity of 79.8 and 78.0, respectively, for the cutoff value ≥4. In the only study validating the Hindi version of S-DN4 in 160 patients, incorporating seven out of ten items of DN4 observed a sensitivity of 88.7% and specificity of 77.5% at the cutoff value of ≥3. The limited sensitivity of Hindi version of DN4 in the present study in comparison to all the aforementioned studies could be attributed to the larger sample size.

The limitation of the study is that the decision of the diagnosis of NP was undertaken by a single expert, wherein, the decision of two experts could have been considered for the diagnosis.

CONCLUSION

The results of the present study utilizing the CH-DN4 questionnaire support the transcultural validity of the DN4 questionnaire. The reliability or inter rate agreement was excellent (0.9), and sensitivity and specificity of the Hindi version of DN4 questionnaire have been found to be 0.78 and 0.76, respectively, at a cutoff point of ≥3.5 (from the 10-item questionnaire) and internal consistency as measured by Cronbach's α was considered sufficient (Cronbach's α = 0.82). Hence, we suggest a multicentric trial with a larger sample size to confirm the findings of the present study.

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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ANNEXURE-II

Appendix A: Questionnaire DN4
Please complete this question-naire by ticking 1 answer for each Item in the 4 questions below:

Interview of the patient

Question 1. Does the pain have one or More of the following characteristics ?

	Yes	No
1.Burning		
2.Painful cold		
3.Electric shocks		

Question 2. Is the pain associated with one or more of the following symptoms in the same area?

	Yes	No
4.Tingling		
5. Pins and Needles		
6.Numbness		
7. Itching		

Examination of the patient
Question 3. Is the pain located in an area Where the physical examination may Reveal one or more of the following Characteristics?

	Yes	No
8. Touch hypoesthesia		
9. Pricking hypoesthesia		

Question 4. In the painful area, can the Pain be caused or increased by:

	Yes	No
10. Brushing		

Appendix B: Hindi Version
प्रश्न १. दर्द किस तरह का महसूस होता है ?

	हां	नहीं
—. जलना		
二. बर्फीला दर्द		
三. बिजली के करंट जैसा		

प्रश्न २. जहाँ दर्द महसूस करते हो वहां कुछ और भी परेशानी होती क्या जैसे ?

	हां	न हीं
四. झनझनाहट होना		
五. सुइयां चलना		
六. सुनपना		
七. खुजली होना		

मरीज की जाँच
प्रश्न ३. क्या दर्द उस जगह महसूस होता है जहाँ जाँच में कुछ और मिले जैसे ?

	हां	न हीं
八. छूने का पता न चलना		
九. सुई चुभाने का पता न चलना		

प्रश्न ४. क्या दर्द वाली जगह पर, दर्द इसके द्वारा बढ़ता है जैसे ?

	हां	न हीं
十. ब्रशिंग		

Annexure II: Complete Hindi version of DN4 questionnaire