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INDONESIAN VERSION OF THE PAINDETECT QUESTIONNAIRE IN THE ASSESSMENT OF NEUROPATHIC PAIN: A VALIDITY AND RELIABILITY STUDY

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ABSTRACT

Objective: *To develop an Indonesian version of PainDETECT Questionnaire (PDQ-Ina) and assess its validity and reliability.* ***Methode:*** *The validity and reliability study was conducted at the Neurology Clinic Cipto Mangunkusumo General Hospital, Jakarta from March 2014 until May 2014 using cross sectional design. Sample of the research was done by non random consecutive sampling method. and were taken from each participant who met the inclusion criteria, measuring reliability of painDETECT Questionnaires (PDQ) using statistical analysis and retest test method within 24-48 hours interval.* ***Result:****There were 150 subjects with chronic pain. Divided in to 3 types of group based on Indonesian version PDQ scoring, 75 patients having nociceptive pain, 42 were mixed pain and 33 patients having neuropathic pain. Within validation criteria analysis there were high correlation between PDQ-Ina with LANSS instrument as gold standard (r= 0,082,p<0,001), AUC 85,5%, sensitivity 78,3% and specificity 78,7% with the optimal cut off point ≥17. The reliability of internal consistency Cronbach's Alpha value were 0,710 and the test retest realibility were 0,96.* ***Conclusion*** *:The Indonesian version of the PDQ is a valid and reliable scale and have a good sensitivity and specificity to be used to determine neuropathic component of chronic pain.*

Keywords: *neuropathic pain; chronic pain; validity dan realibility; painDETECT quesstionnaire*

ABSTRAK

Tujuan: Menciptakan Kuesioner PainDETECT (PDQ-Ina) versi Indonesia dan menilai validitas dan reliabilitasnya. Metode: Uji validitas dan reliabilitas dilakukan di Klinik Neurologi RSUD Cipto Mangunkusumo, Jakarta dari bulan Maret 2014 sampai Mei 2014 dengan metode cross sectional. Pengambilan sampel penelitian dilakukan secara non random consecutive sampling. dan diambil dari masing-masing partisipan yang memenuhi kriteria inklusi, mengukur reliabilitas kuesioner painDETECT (PDQ) menggunakan analisis statistik dan metode tes ulang dalam interval 24-48 jam. Hasil – Terdapat 150 subjek dengan nyeri kronis. Dibagi menjadi 3 kelompok berdasarkan skoring PDQ versi Indonesia, 75 pasien nyeri nosiseptif, 42 nyeri campuran, dan 33 pasien nyeri neuropatik. Dalam analisis kriteria validasi terdapat korelasi yang tinggi antara PDQ-Ina dengan instrumen LANSS sebagai gold standard (r = 0,082, p <0,001), AUC 85,5%, sensitivitas 78,3% dan spesifisitas 78,7% dengan cut off optimal. poin ≥17. Reliabilitas konsistensi internal nilai Cronbach's Alpha sebesar 0,710 dan realibilitas tes retest sebesar 0,96. Kesimpulan: PDQ versi Indonesia adalah skala yang valid dan dapat diandalkan serta memiliki sensitivitas dan spesifisitas yang baik untuk digunakan dalam menentukan komponen neuropatik dari nyeri kronis.

Kata Kunci: nyeri neuropatik; nyeri kronis; validitas dan reliabilitas; kuesioner painDETECT

Introduction

Chronic pain is a complex biopsychosocial phenomenon. An epidemiological study defines chronic pain as pain that lasts more than 3 to 6 months with persistent pain intensity, impact on all aspects of economic, psychosocial and quality of life as one of the biggest health problems in the world for patients seeking medication. [1, 2]Results of a multicentre study in Canada and the United States showed 78% of patient with pain visits the Emergency Room. [2] Estimation chronic pain prevalence population-based study reported 2-55% in the world.[3] For Southeast Asia like Thailand is up to 17.5%, Singapore 8.7% and the Philippines 10.4%

with a mean annual incidence of 3.4% .[4,5,6] Indonesia itself based on the results of a multicenter study from 14th Teaching Hospital Outpatient, Indonesian Neurologist Association Studygroup for Pain in 2002 obtained 4,456 cases pain which 9.5% were neuropathicpain.[7] The prevalence of statistical data in the world that neuropathic pain component ranged 0.9 - 17.9% with 8.2 per 1000 population incidence peryear.[8] The country's financial burden caused by chronic pain are enormous including the cost of medical care, payment of damages and lost work productivity. In the United States an estimated total health expenditure ranges from 560 billion to 635 billion USD peryear.[9] Neuropathic pain is known as one of the most difficult to overcome in the level of primary health care, and often underdiagnose lead to suboptimaly treatment.[9,10]

Absence of the ideal screening instruments of a neuropathic components made it difficult to recognize the cardinal signs of neuropathic pain.[11,12] Several screening tools for distinguishing neuropathic pain from non-neuropathic pain have been developed in the world, but is still under debate. The application of screening tools in a large population of criteria instruments require a short, easy and simple. PainDETECT Questionnaires, as an instrument of short, self-report has been validated in Germany in 2006 and applied in 8000 patients with chronic low back pain.[11] This questionnaire has been validated in Spain, Turkey and Japan, and was translated into 19 language in the world. Has a good sensitivity and specificity. This questionnaire serves as an effective pain descriptors in identifying components of neuropathic pain and as a first step in giving the proper treatment in managing pain.[12,13,14]

Given the magnitude of the impact from chronic pain in the society, this questionnaire has an important role in helping to identify the type of pain. Based on this study into Indonesian carried out, that evidently reliable to be applied in Indonesia and can be used both by neurologists and or general practitioners in the first level health care in pain assessment for neuropathic pain component.[15]

Material and Methods

The study protocol was approved by the institutional review board of the Clinical Research Support Center of the University of Indonesia, Cipto Mangunkusumo Hospital (CMH). Participants provided their written informed consent to participate in this study.

The validaton study referring from Criterian Validation based on concurrent criteria compares with the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) questionnaire as the parameter gold standard. And reliability studies of the painDETECT questionnaire Consists of internal consistency and

reliability test retest using Alpha Cronbach and product moment pearson correlation statistical analysis.using the SPSS version 21.0 .

The study population was all patients with chronic pain based on inclusion criteria during the study and have the basic pathophysiology of neuropathic pain and nociceptive pain. Each participant who met the inclusion criteria and were willing to follow the research put into the research sample. Aged ≥ 18 years Understand and be able to speak Indonesian, Can read and write does not depend on others, sustained pain ≥3 months, intensity scale NRS>3, Patients who during a visit with or without analgesic treatment. We exclude Patients who don't have primary pathophysiology of neuropathic pain and nociceptive pain. Patients with a diagnosis of psychotic disorder or psychosomatic, Patients with moderate to severe depression according to Hamilton Scale, Patients with symptoms of headache, fibromyalgia, and refuse to participate in this research

Linguistic Adaptation

Translation and cross-cultural adaptation of the PDQ into Indonesian was carried through of stages based on the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) process for the adaptation and validation of patient-reported questionnaires . The adaptation procedure was supervised by an expert committee including experts in pain medicine and expert in methodology and validation of instruments.(The questionnaire translation has been published In a separate study in Indonesia)

Leeds Assessment of Neuropathic Symptoms and Signs (LANSS)[16,17,18,19]

LANSS is believed to be the instrument of neuropathic pain assessment tool. Consisting of 5 the question of symptoms and 2 clinical examination. This tool has a sensitivity of 82-91% and a specificity of 80-94%. Regarded as the gold standard instrument due to its ability to detect components of neuropathic pain. In its application, this instrument involves the clinician to examine sensibility.Total score of assessment instruments, maximum 24. If the score under 12, the mechanism seems considered to be suggestive non-neuropathic pain[16] . And score is 12 or greater, considered to be suggestive neuropathic pain

Validation Study[17,18,19]

The validity criteria done by correlating a measuring instrument with the other criteria are considered the gold standard. Increasingly steeper the better correlation validity The combination of optimal sensitivity and specificity shown in curve Receiver Operating Characteristics (ROC). ROC procedure will be obtained from the value of area under the curve (AUC). ROC is usually wider area, the optimal

combination of sensitivity and specificity,the generally accepted correlation for coefficients: 1.0–0.81 (excellent); 0.80–0.61 (very good); 0.60–0.41 (good); 0.40–0.21 (fair); and 0.20–0 (poor).

Reliability Study

Reliability Internal Consistency, measuring instruments used to provide consistent value mesurement repeatedly. Reliable measurement tool not only shows internal consistency, but also the stability when used to measure variables research subject to conditions that are identical. Internal consistency was measured with Cronbach's alpha. Alpha coefficients of a magnitude of ≥0.70 were considered useful as evidence of adequate scale reliability at the level of group comparisons.

Reliability test Retest done by trying measuring devices multiple times to the same respondents with the same instrument in a different time interval. Reliability measured by the Intraclass correlation coefficients (ICCs) analysis between test and retest scores. The measuring instrument has sufficient stability if ICC between measurements> 0.50, which categorizd poor if ICC between 0,01-0,40 and Reach high stability if ICC between measurements ≥ 0.80 (Streiner and Norman, 2000; Polgar and Thomas, 2000).

Table 1. Demographic data of study subjects

Data	N (%)
Age (Year)	50,97±11,16
Age Group	
18-45yr	41 (27,3)
46-60 yr	83 (55,3)
≥61yr	26 (17,3)
Gender	
Man	29 (19,3)
Women	121 (80,7)
Education Level	
Low	16 (10,7)
Middle	115 (76,7)
High	19 (12,7)
Occupation	
Field occupation	93 (62,0)
House wife	31 (20,7)
Office	18 (12,0)
No work	8 (5,3)

RESULT

A total of 162 Indonesian patients were recruited in this study. However, twelve patients were excluded from the analysis because didnt fit the inclusion criteria and has an incomplete responses,. Following exclusions, a total of 150 patients were further evaluated. The demographic characteristics of the study subjects Of the 150 subjects research shows the majority of respondents were female (80.7%) and secondary education (76.7%). the age group 46-60 years as the largest age group (55.3%) with a mean age of 50.9 years old respondents. And most of the status of the field workers (62.0%).

Classification of pain based on the PDQ scores, where 75 subjects (50%) suffered from nociceptive pain, 42 subjects (28%) suffered from a mixed pain and 33 subjects (22%) of neuropathic pain. Similar to the measured result using LANSS instruments, where 127 subjects (84.7%)

with non-neuropathic pain and the remaining 23 subjects with neuropathic pain. A comparison of the total score either measured with PDQ obtain score of 12.5 and LANSS score was 10, which placed non-neuropathic pain as the majority of the group compared to the neuropathic pain group in the concept, giving the same measurement to sreen neuropathic component.(Table 1; Figure 1, 2)

Figure 1. Pain types proportion based on PDQ score

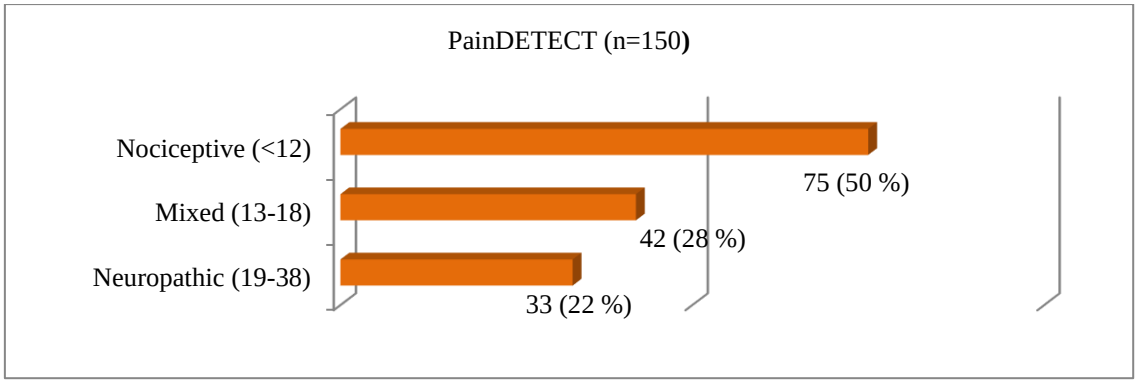
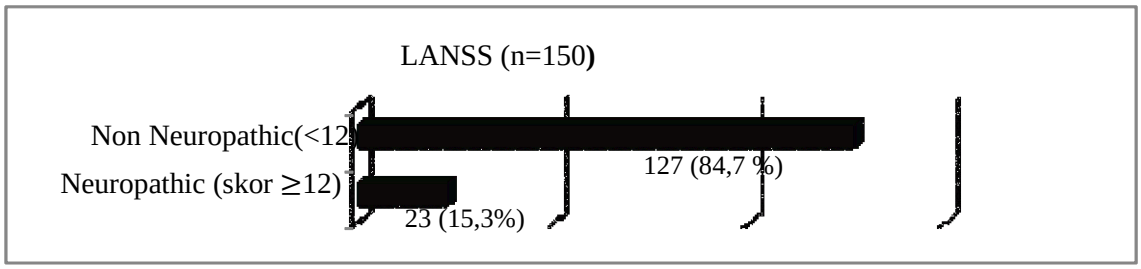


Figure 2. Pain types proportion based on LANSS score



Comparing the classification types of pain based on PDQ with directly proportional to etiology.Grouping type of pain based on table. 3, as the following results: the nociceptive pain group obtained 34.7% of subjects with chronic back pain, 18.7% of osteoarthritis genu and 5.3% of shoulder and arm pain. In the mixed pain group obtained 38.1% with lumbar radiculapathy, 24.2% of cervical radiculopathy. In the group of neuropathic pain obtained 18.2% Diabetic polyneuropathy, 3% trigeminal neuralgia, but the scoring result PDQ put 3% of entrapment neuropathy in the group of nociceptive pain.(Table 2)

Table 2. Results of examination with PDQ and LANSS

Data	N (%)
PainDetect Total score (n=150)	12,5 (2,5-23,5)
PDQ pain Classification(n=150):	
• Nociceptive(<12)	75(50,0)
• Mixed (13-18)	42(28,0)
• Neuropathic (19-38)	33(22,0)
PainDetect retest total score (n=30)	13,5 (2-23)
PainDetect retest pain Classification (n=30):	
• Nociceptive(<12)	12(40,0)
• Mixed (13-18)	12(40,0)
• Neuropathic (19-38)	6(20,0)
LANSS Total score(n=150)	10 (1-15)
LANSS pain Classification(n=150)	
• Non Neuropathic (skor <12)	127(84,7)
• Neuropathic (skor≥12)	23(15,3)

In the extrapolation scores using LANSS in determining types of pain, found the comparison score between nociceptive group (= non neuropathic / NNP) with mixed pain group (NNP vs. NC) and a comparison score between nociceptive with neuropathic (NNP vs. NP) Or a mixed pain group with neuropathic pain group (NP vs. NC) values obtained statistically significant (Mann-Whitney Post hoc: with p <0.001).Statiscally figuring Where PDQ scores on nociceptive pain group obtain 8.08 (SD 3.45), mixed pain group 14.55 (SD 2.38) and neuropathic pain group 20.57 (SD 1.62) (Post hoc Tamhane value p <0.001). And correlation between the scores of PDQ with LANSS statistically obtained value of Pearson correlation r = 0.820.(Figure 3)

The validity of PDQ based on Area Under the Curve (AUC) will be indicated by the curve cut off point consisting of Sensitivity and specificity related to the current validation content . Both, Sensitivity and specificity are used to assess the validity of an instrument coincide which is considered the gold standard gauge.The optimal combination of both are shown on the Receiver Operating Characteristic (ROC) curve, then AUC values which will be obtained. The wider the area of ROC Curve, the more optimal combination of sensitivity and specificity.(Figure 4). However, if the Attainment of sensitivity is to high, generally specificity will deteorated. Then required a further statistical analysis using an effective cuttoff point in order to produce an ideal value. Sensitivity depicted on the ordinate Y, whereas (1-specificity) is plotted on the abscissa x. This research shows the ROC curves away from the line of 50% and nearly 100% (Figure 5)

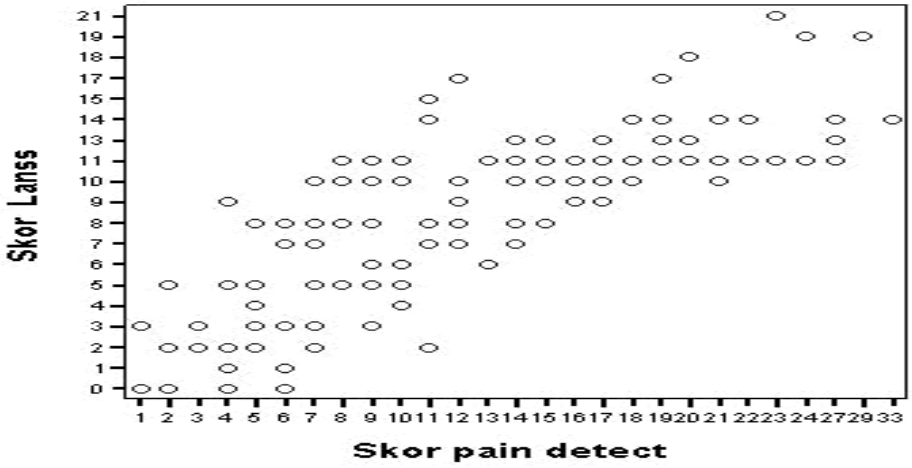
Table 3. Etiology type of pain Based On Ina-PDQ

	Nociceptive (0-12) A(n=75)	Mixed (13-18) B(n=42)	Neuropatik (19-38) C(n=33)	*P* value
Nociceptive Pain:				
Chronic Back Pain	26 (34,7)	6 (14,3)	1 (3,0)	
Osteoathritis Genu	14 (18,7)	0 (0,0)	0 (0,0)	
Shoulder and arm pain	4 (5,3)	0 (0,0)	0 (0,0)	
Mixed Pain:				
Lumbal Radiculopathy	12 (16,0)	16 (38,1)	11 (33,3)	<0,001*
Cervical Radiculopathy	0 (0,0)	5 (11,9)	8 (24,2)	
Carpal tunnel syndrome	18(24)	12(28,6)	6(18,2)	
Neuropathic Pain:				
DiabetesPolyneuropathy	0 (0,0)	3 (7,1)	6 (18,2)	
Trigeminal Neuralgia	0 (0,0)	0 (0,0)	1 (3,0)	
Entrapment Neuropathy	1 (1,3)	0 (0,0)	0 (0,0)	

Comparison of proportions was tested by Chi square, a numerical comparison of normal distribution with one way ANOVA test, a numerical comparison is not normal distribution with the Kruskal-Wallis test.
* Post hoc Chi square: A vs. B p <0.001; A vs. C p <0.001; B vs. C p = 0.144.

AUC PDQ value compared against LANSS score was 85.5% (CI 95% from 0.780 to 0.930) with p <0.001. And based on confidence intervals (CI), note that the AUC PDQ score in patients with neuropathic pain component ranges between 78 to 93%. If the instrument intended functionate as a screening tool for neuroptic pain components, a cutoff point with a high sensitivity value is Required

Figure 3. Correlation between PainDETECT and LANSS score



From the table cuttoff point possibilities (Table 4) Reached point range as follows,that Optimal cut-off point stood at ≥17, that attainment sensitivity of 78.26% and a specificity of 78.74%. When using a two-point cut by involving mixed pain group

into a group of neuropathic pain then Perched on ≥13 as the point of intersection with 86.96% sensitivity and 56.69% specificity, while in the intersection ≥19 showed 69.57% sensitivity and 86.61% specificity.

Table. 4. The Sensitivity And Specificity of Several Possibilities

Correctly Cutpoint	Sensitivity	Specificity	Classified	LR+	LR-
>=12	91,30%	52,76%	58,67%	1,9326	0,1648
>=13	86,96%	56,69%	61,33%	2,0079	0,2301
>=14	86,96%	58,27%	62,67%	2,0837	0,2239
>=15	82,61%	67,72%	70,00%	2,5589	0,2568
>=16	78,26%	74,02%	74,67%	3,0119	0,2937
>=17	78,26%	78,74%	78,67%	3,6812	0,2761
>=18	73,91%	83,46%	82,00%	4,4700	0,3126
>=19	69,57%	86,61%	84,00%	5,1969	0,3514
>=20	56,52%	89,76%	84,67%	5,5217	0,4844

Figure 4. ROC Curve

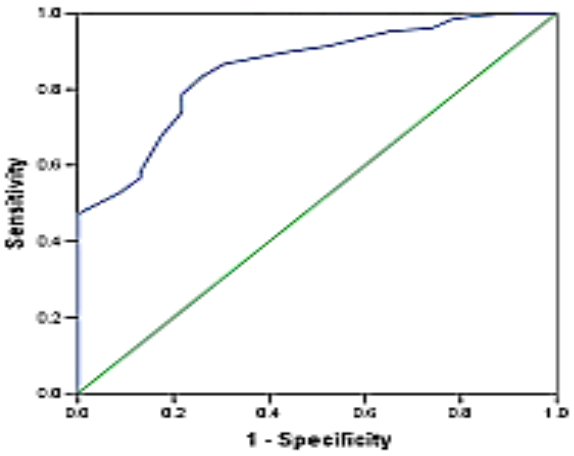
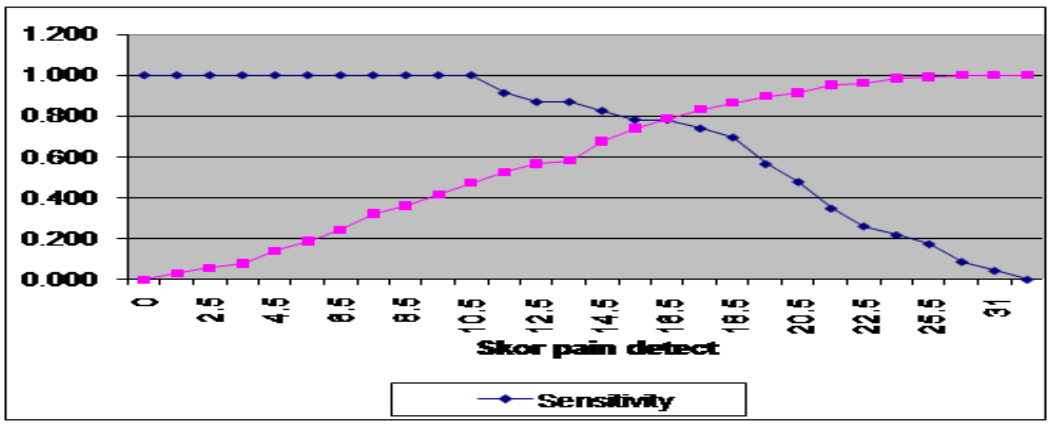


Figure 5. Procedures for determining the optimal cut point



Based on 2x2 extrapolation Table (Table 5) in assessing current validity Against the gold standard score by using the cutoff point ≥17, where 0-16 = non neuropathic; 17-38 = neuropathic with a sensitivity of 78.26% and a specificity of 78.74%. Can be obtained positive predictive value and negative predictive value also.(Table 6)

Result of the internal consistency extrapolation between the grains in the total score of the PDQ, for the entire item questionnaire other than pain intensity questions in NRS, were Cronbach Alpha 0.710.

Table 5. PainDetect Diagnostic value

		Neuropathic ≥12	Non Neuropathic <12	Total
PDQ score	≥17	18	27	45
	<17	5	100	105
		23	127	150

Table 6. Diagnostic parameters

Diagnostic parameters	Value (CI 95%)
Sensitivity	78,3 (56,3-92,5)
Specificity	78,7 (70,6-85,5)
Positive predictive value / PPV	40,0 (25,7-55,7)
Negative predictive value /NPV	95,2 (89,2-98,4)
Positive likelihood ratio	3,68 (2,47- 5,48)
Negative likelihood ratio	0,276 (0,126-0,603)

In this study, test retest reliability of 30 subsamples sufferers from chronic pain using a PDQ within 24-48 hours. During the replenishment of the questionnaire each respondent was accompanied and evaluated. The relationship between the results of the first survey and the second survey of PDQ explained in the Bland-Altman correlation (Figure 6).

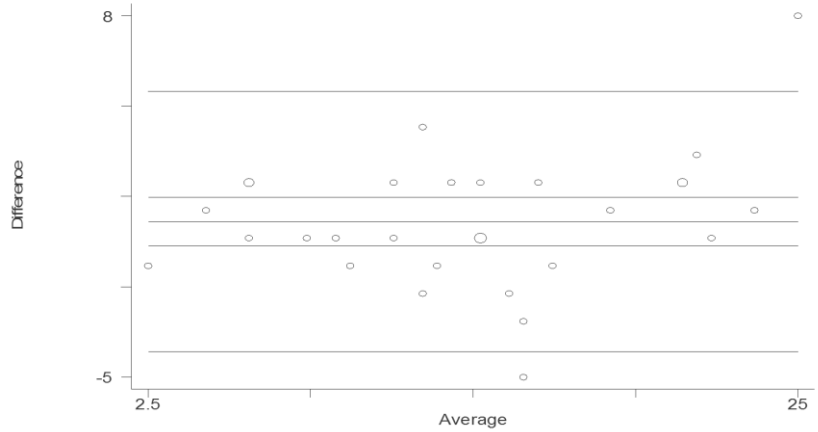
Stability overtime was assessed by extrapolating the correlation coefficient interclass (= ICC). The mean total score PDQ (n = 150) was 12.5 (2.5 to 23.5), while the mean total score PDQ Retest (n = 30) was 13.5 (2 to 2.3). ICC between the two scores based on Limits of agreement: -4.086 to 5.286; the mean difference: 0,600 (CI 5% -0,275- 1.475). ICC gives 0,960 results (0.915 to 0.981).

DISCUSSION[20,21,22]

This study demonstrated that PDQ-Ina has good validity and reliability. In addition, the results obtained in this study were comparable with those obtained in previous studies Based on a statistical analysis of this study, a sensitivity of 78.3% and a specificity of 78.7%. With a value of 85.5% AUC (CI 95% from 0.780 to 0.930), *p* <0.001, is quite good. AUC value of 85.5%

means that if a PDQ score used to screen components of neuropathic pain in 100 patients then obtained the proper conclusion in about 85 patients.

Figure 6. Bland-Altman correlation between the total score of painDETECT With a total score of painDETECT test retest



Referring to the original version of the PDQ study Freynhagen et al. in populations with chronic low back pain found sensitivity and specificity and positive predictive value of 85%, 80% and 83% respectively with a 91% AUC values. In the study used two-point cut to screen for neuropathic pain component is ≤12 with a negative predictive value of 85% and ≥19 with NPP 90% .

Spanish version of the study were similar to our study on chronic pain in general, when using a 2 point cut as in the original version, the figures obtained ≤12 likelihood ratio (LR) or a positive likelihood ratio of 85% instead of neuropathic (NPN 80%) whereas ≥19% neuropatk LR90 (NPP 92%). The analysis only on neuropathic pain assessment between groups with non-neuropathic group. AUC value of 87.9% (IK95% from 0.820 to 0.937), p <0.001. If the group involves mixed pain in neuropathic group obtained ≤15 cut points with sensitivity 83.7%, specificity 78.3% and the NPP 90%. Then searched the optimal cut point without involving a mixture of pain group at ≤17 figures as a single cut-off point to obtain the sensitivity and specificity of 81.2% for both.[17,18,19]

In the study involving the Turkish version without pain group mix using 2 point cut the original version with the cutoff point ≤12 obtained sensitivity, specificity and NPP sequentially 90%, 67.5% and 87%. When using a cutting point ≥19 obtained sensitivity, specificity and NPP sequentially 77.5%, 82.5%, 82%. Then searched the optimal cut point without involving a mixture of pain group at ≤17 figures as a single cut-off point to obtain the sensitivity and specificity of 81.3% and 80%. With a 89% AUC values. If the group involves a mixture of pain in neuropathic group

obtained ≤14 point of intersection with the sensitivity and specificity of 79.4% and 75%.

In this study if it involves pain group mixture into neuropathic group then obtained ≥13 the point of intersection with 86.96% sensitivity and specificity of 56.69%, while in the intersection ≥19 obtained sensitivity and specificity 69.57% 86.61% .In this study, the value of a single cut-off point which is considered optimal as a screening instrument components neuropathic pain is <17 as the limit of non neuropathic pain and neuropathic pain ≥17 as a limitation that has a sensitivity of 78.26% and a specificity of 78.74%, based on the gold standard screening LANSS .

In this study, conducted tests retes at 30 subsamples within a period of 24-48 hours, the mean total score painDETECT obtained (n = 150) was 12.5 (2.5 to 23.5), while the mean total score painDETECT retes (n = 30) 13.5 (2 to 2.3). Retes test the reliability of the correlation calculations in this study was 0.96.

In the Turkish version of the study obtained painDETECT total mean score of 16.33 (SD 8.35) and 15.9 (SD 8.17) on the score retes. And test the reliability obtained retes ICC calculation 0.98. Stability overtime while the Spanish version of the 26 subsample obtained painDETECT total mean score of 14.3 (SD 9.2) and 13.5 (SD 9.0) in the score retes. In tests of reliability obtained ICC retes 0.93.[17]

In the Japanese version of the study involved 16 subsamples retes within 23 days in painDETECT get a total score of 20.4 (SD 7.7) and 20.2 (SD 7.2) on the score retes. Obtained ICC relations between the two scores is 0,94.18 Said of a measuring instrument has adequate stability when ICC> 0.5 and have high stability when ICC> 0,8. [18]

Referring to research conducted Freynhagen in 2006 in Germany. The original version did not perform tests on the questionnaire painDETECT retes due to ethical reasons. Interrupting the administration of drugs in patients with chronic low back pain is considered scientific injustified. Pain is considered to be subjective and tend to change the coefficient stability tests retest considered in the assessment of the limitations.[14]

But after a large study of lower back pain is done, following a retrospective analysis research test retest reliability involving 94 patients with criteria of low back pain for more than 6 months, and pain intensity between visits of less than 5 NRS scale. Retes tests conducted within 7-21 days with a mean of 15 days between the grains showed ICC ranged from 0.65 to 0.80 while the ICC painDETECT score was 0.87. The study is considered valid and reliable and can be used as an instrument for follow-up of patients.

Conclusions:

Instruments screening component of neuropathic pain painDETECT Indonesian version has a high correlation to the instrument LANSS which is considered as the gold standard screening tools for neuropathic components. Indonesian version of painDETECT screening tools has been proven reliable based on test retest study, having the single cutt off point ≥17 as the optimal value in sifting component of neuropathic pain and has a good sensitivity and specificity also.

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