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Validation analysis of Polish version of Neuropathic Pain Questionnaire — Short Form (NPQ-SF-PL) and assessment of quality of life in patients with chronic neuropathic pain

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ABSTRACT

Aim of the study. The aims of this study were to translate and culturally adapt the Polish version (PL) of the Neuropathic Pain Questionnaire-Short Form (NPQ-SF), as well as to compare this questionnaire to other diagnostic tools in terms of reliability and psychometric validity.

Clinical rationale for the study. Neuropathic pain (NP) affects up to 10% of the general population. Despite a large number of studies, almost 50% of patients have a poor therapeutic outcome. Diagnostic tools are intended to distinguish between NP and non-NP (NoP) and to guide the examiner to perform further diagnostics in accordance with the guidelines.

Material and methods. A total of 140 patients with chronic pain (ChP), 90 with NP and 50 with NoP, were enrolled into this study. NPQ-SF-PL has been developed following the guidelines for translation and cultural adaptation. Reliability of the translated version was examined using internal consistency, predictive validity, and intraclass correlation coefficient (ICC).

Results. In the study, women predominated over men, and the average age was 53.22. Cronbach's α value for the entire scale was 0.76 and ICC for test-retest reliability was 0.631. Receiver-operating characteristic curve analysis gave a sensitivity of 90.0% and a specificity of 88.0%. Area under the curve was 0.94. NPQ-SF-PL was moderately associated with self-completed Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) and weakly associated with the Numerical Rating Scale (NRS). The NP group obtained statistically significantly lower scores than the NoP group in all domains of the 36-Item Short Form Health Survey (SF-36), thus indicating worse health status. Patients aged over 41 years presented a worse quality of life compared to younger ones. Also, more than half of the patients with NP of both genders experienced symptoms of mild or more severe depression.

Conclusions. NPQ-SF-PL is a valid screening tool for assessing NP in Polish chronic pain patients. The obtained results showed very good psychometric properties and adequate internal consistency. The repeatability of the questionnaire indicated moderate reliability.

Clinical implications/future directions. We believe this study will provide physicians with a new instrument for the evaluation of NP for clinical and research purposes.

Keywords: aging, cross-cultural adaptation, depression, diagnostic tool, neuropathic pain, Neuropathic Pain Questionnaire, non-neuropathic pain, Quality of Life

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Introduction

Neuropathic pain (NP) is a condition that affects 7–10% of the general population. In patients with diabetes, this can be as much as 20–30%. The latest cross-sectional cohort UK Biobank data indicates a NP prevalence of 9.2%, accounting for 18.1% of people with chronic pain (ChP). Despite a large number of studies and analysis, almost 50% of patients have a poor therapeutic outcome i.e. they either do not respond to the proposed treatment or the response is only moderate at best. Therefore, NP should be considered as a major unmet clinical need [1, 2]. Increased sensitivity to pain, or spontaneous pain in paradoxical combination with reduced or loss of function, may be a consequence of damage to the somatosensory nervous system. This happens in the case of NP, which often later becomes chronic, i.e. lasting ≥ 3 months, and manifests in recurrent pain episodes or persistent pain [3, 4].

According to the International Association for the Study of Pain (IASP) classification, chronic NP consists of peripheral and central pain. The first type combines units such as postherpetic or trigeminal neuralgia, nerve lesions, painful neuropathy, and radiculopathy. The 'central pain' category includes sequelae of diseases such as multiple sclerosis, stroke, and brain or spinal cord injury [3]. The most characteristic features of NP, regardless of its aetiology, are ongoing pain, paroxysmal pain, and allodynia. These result from various pathophysiological mechanisms [5].

To guide clinical decisions, a three-level grading system for certainty of NP has been designed: possible, probable, and definite. The 'possible' level of certainty contains the use of screening tools because a combination of several different descriptions has high distinctive value and may be indicative of NP. It is indispensable that the patients' history indicates neurological disease or lesions with an anatomically related pain distribution [6]. Diagnostic tools are also intended to distinguish between NP and non-NP; nevertheless, they should not be used in patients with widespread pain [7]. Also, their use alone does not enable the identification of a patient with NP, but is intended to direct the examiner to carry out further diagnostics, in accordance with the guidelines [6]. The subsequent full examination for NP can be time-consuming but is extremely important for initiating appropriate treatment. Therefore, a practical, quick and easy screening assessment is very helpful [8, 9].

At the same time, pain has a complex impact on the patient's life, and can lead to physical, mental and even spiritual suffering. Fighting pain should always be a priority, but even so coping strategies can also help to manage and reduce the consequences of pain [10]. Biological and genetic factors appear to underlie the co-occurrence of NP and mental illness. On the other hand, some behavioural and social factors can be modified by patients themselves and seem to be important in the prevention of NP [11].

Having considered the above, physicians should actively recognise and treat pain and its complications, as well as encouraging and supporting the patient in finding appropriate coping strategies.

Clinical rationale for the study

To the best of our knowledge, the Neuropathic Pain Questionnaire-Short Form (NPQ-SF) has never been translated into or validated for the Polish language. The aims of this study were to translate and culturally adapt the Polish version of the NPQ-SF, as well as to compare this questionnaire to other diagnostic tools in terms of reliability and psychometric validity.

Material and methods

This single-centre prospective observational study began in January 2021 and was conducted over 24 months in the University Clinical Hospital No. 4 in Lublin, affiliated to the Medical University of Lublin, Poland. A total of 140 ChP patients who met the eligibility criteria were included in the study. All patients had previously been assessed for pain type (i.e. NP, non-neuropathic pain, or other) according to the IASP guidelines. The following inclusion criteria were adopted: (1) age 18 years or over; (2) men or women with ChP for ≥ 3 months; (3) patients able to speak and read Polish; and (4) patients expressing written consent to participate in the study. In order to obtain sociodemographic data and medical history, an interview was conducted with each patient. In cases of cognitive or communication impairments that prevented the completion of the questionnaire, as well as a previous history of severe psychiatric diseases, patients were excluded from the research. Additional exclusion criteria were an unidentifiable nerve injury and pain syndromes associated with diffused pain. Study participants obtained all relevant information about this research and provided written informed consent before undergoing screening. If patients had any doubts about completing the survey, the physician explained the content of the survey and/or clarified the type of pain. Ethical approval to conduct this study was obtained from the Institutional Ethics Committee of the Medical University of Lublin, Poland (KE-0254/147/2020).

Instruments

The NPQ-SF [12] is a self-report assessment consisting of three items; tingling pain, numbness, and increased pain due to touch. These three have been selected from the original Neuropathic Pain Questionnaire (NPQ) [13]. These three items are significant predictors able to distinguish NP from non-NP (NoP) and are consistent with clinical symptoms and signs (positive and negative phenomena) occurring in NP [14].

For each item, participants numerically rate their usual pain on a scale of 0 (i.e. none) to 100 (the worst pain imaginable). To obtain a total discriminant function score, the results for each item are multiplied by the coefficient of the discriminant function and the structure coefficients, and then summed up using a given constant value. Thus, a result ≥ 0 predicts NP, while scores below 0 denote NoP. NPQ-SF is characterised by sensitivity of 64.5% and specificity of 78.6%, and total predictive accuracy of 73.0%. The NPQ-SF has been translated into and validated for the Turkish [8] and Arabic [15] languages.

In order to make comparisons between NPQ-SF and some commonly used scales, the Polish version of the NPQ-SF (the NPQ-SF-PL) was administered to patients, together with the self-completed Leeds Assessment of Neuropathic Symptoms and Signs (S-LANSS) [16, 17], the Numerical Rating Scale (NRS) [18], the Hamilton Rating Scale for Depression (HRSD) [19], and the 36-Item Short Form Health Survey (SF-36) [20]. For the purpose of test-retest reliability evaluation, 50 of the patients filled out the NPQ-SF-PL for a second time after 14–21 days.

Translation and cross-cultural adaptation

Translation and cross-cultural adaptation followed the guidelines proposed by Beaton et al. [21]. The NPQ-SF-PL was first developed by forward translation of the original version of the questionnaire by two independent bilingual translators with different profiles whose native language is the target language (i.e. in this case Polish). The second step was to create one common translation from these two translations. Blind back-translation was then performed by two professional translators, and the resulting versions were evaluated and compared to the original version of the tool. The unified, pre-final version of the tool was tested by patients in order to look for a missing element or unclear sentence. The final version, re-evaluated based on the reports obtained, was approved and accepted by the participating scientists and validated in clinical settings. Permission to translate the NPQ-SF into Polish was granted by Dr Miroslav Bačkonja, who created the original version of this tool.

Statistical analysis

Statistical analysis was performed with Statistica software (version 13.3, StatSoft, Lublin, Poland). Data expressed on a qualitative scale was presented as number or mean, standard deviation (SD) and interquartile ranges (IQRs). For statistical significance, a value of $p < 0.05$ was assumed. Regardless of missing data, patients were included in the analysis if the entire NPQ-SF was completed. Incomplete or unclear data from other questionnaires used was omitted from statistical analysis. Frequencies and descriptive statistics were examined for each variable. Statistical comparisons were made between the NP and NoP subgroups in terms of demographic characteristics and the results of individual questionnaires. A chi-squared test (χ^2) was used to compare the relationships between variables expressed on a qualitative scale. A non-parametric Mann-Whitney U test was used to compare the means of two independent samples and Dunn's multiple comparison tests to evaluate differences among the groups. Also, to measure reproducibility and consistency of results, test-retest reliability was performed with the intraclass correlation coefficient (ICC) with corresponding 95% confidence intervals (CI) between first and second total scores [22]. The Cronbach's alpha (α) coefficient was calculated to analyse the internal consistency of this 3-item questionnaire. Internal consistency indicates the degree of correlation between the items and is the measure of scale homogeneity. Alpha is assumed to be from 0 to 1, but given a negative correlation between elements, the reliability result may be below 0. Some authors recommend a maximum value of 0.90 to avoid redundancy among the items. A Cronbach's alpha of > 0.80 indicates good internal consistency [23, 24]. To assess the relationship between variables and to calculate the correlation between different scales, we used Spearman's correlation coefficient (R). The relations were interpreted as strong (0.7–0.9), moderate (0.4–0.6), or weak (0.1–0.3) [25]. The predictive validity was estimated using receiver operator characteristic (ROC) curves. The area under the curve (AUC), and its 95% CI for the ROC curve, were calculated. Also, to maximise the sum of sensitivity and specificity for all the possible values of the cut-off point, the Youden index was calculated [26].

Results

The final version of the NPQ-SF-PL is attached as Supplementary material.

General information

The study group consisted of 140 patients with ChP of differing origins. Patients with NP accounted for 64.29% and patients with NoP for 35.71%. The mean age (SD) of patients was 53.22 (15.81). There was no significant difference between the gender distribution of the two groups ($p > 0.05$). A significant relationship was found between the place of residence distribution ($p < 0.05$), with the NP group predominantly living in towns/cities and the NoP group in the countryside. Detailed data on the clinical and demographic characteristics of the NP and NoP groups is set out in Table 1, and can be found in our previous article concerning validation of the Polish version of the NPQ [27]. According to Yates's chi-squared test, a statistically significant difference in the occurrence of NP by using NPQ-SF-PL was obtained between the study group and the control group ($p < 0.05$). The average NPQ-SF-PL score (SD) for the total group was –0.09 (0.97). The NPQ-SF-PL was compared to different questionnaires. There was no statistically significant difference between the assessment of the NP group in NPQ-SF-PL compared either to the S-LANSS questionnaire or to the NRS.

Table 1. Brief clinical and demographic characteristics of whole group

	NP n = 90	NoP n = 50	Female n = 85	Male n = 55
Mean age (SD)	55.82 (15.26)	48.54 (15.87)	52.42 (16.44)	54.45 (14.85)
Gender F/M	53/37	32/18		
Diagnosis	– central pain (n = 15) – CIDP (n = 9) – metabolic neuropathy (n = 17) – malignant neuropathy (n = 9) – trigeminal neuralgia (n = 4) – postherpetic neuralgia (n = 3) – painful polyneuropathy (n = 8) – painful radiculopathy (n = 25)	– primary or secondary musculoskeletal pain (n = 25) – primary or secondary headache or orofacial pain (n = 7) – primary or secondary visceral pain (n = 6) – cancer-related pain (n = 3) – postsurgical or post-traumatic pain (n = 9)		
NPQ-SF-PL score (SD)	0.41 (0.81)	–0.99 (0.38)	–0.002 (1.04)	–0.23 (0.82)
HDRS score (SD)	10.37 (8.04)	6.92 (7.15)	9.28 (7.74)	8.90 (8.17)

CIDP — chronic inflammatory demyelinating polyneuropathy; F — female; HDRS — Hamilton Depression Rating Scale; M — male; NoP — non-NP; NP — neuropathic pain; NPQ-SF — Neuropathic Pain Questionnaire short form; SD — standard deviation

Table 2. Mean scores obtained by using Hamilton Depression Rating Scale (HDRS) divided into tested (NP) and control (NoP) groups

HDRS scores (meaning)	NoP group	NP group					
	Total (%)	Total (%)	Females (%)	Males (%)	21–40 years (%)	41–60 years (%)	61+ years (%)
0–6 (no depression)	31 (62.00)	42 (46.67)	25 (47.17)	17 (45.94)	9 (50.00)	15 (46.88)	17 (42.50)
7–12 (mild depression)	8 (16.00)	11 (12.22)	5 (9.43)	6 (16.22)	2 (11.11)	4 (12.50)	6 (15.00)
13–17 (moderate depression)	7 (14.00)	20 (22.22)	13 (24.53)	7 (18.92)	4 (22.22)	8 (25.00)	8 (20.00)
18–29 (severe depression)	3 (6.00)	14 (15.56)	9 (16.98)	5 (13.51)	2 (11.11)	3 (9.37)	9 (22.50)
30–52 (very severe depression)	1 (2.00)	3 (3.33)	1 (1.89)	2 (5.41)	1 (5.56)	2 (6.25)	0 (0.00)
Total	50 (100.00)	90 (100.00)	53 (100.00)	37 (100.00)	18 (100.00)	32 (100.00)	40 (100.00)

Hamilton Depression Rating Scale (HDRS)

At enrollment in this study, patients were evaluated using the HDRS. The average HDRS score (SD) was 9.14 (7.89). Dividing into NP and NoP groups and into genders gave higher HDRS results for the NP group and for women [27]. There was no significant difference in the level of depression between the NP and NoP groups ($p > 0.05$). Taking into account only the NP group, there was no statistically significant difference in the level of depression between women and men ($p > 0.05$) or between respondents depending on age ($p > 0.05$) (Tab. 2). Nevertheless, according to the results, most NP patients of both genders experienced symptoms of mild or more severe depression, which is noteworthy. For the group of women this figure was 52.83%, and for men 54.06%. We also noted an increase in the incidence of depression with the increasing age of respondents, with the highest percentage of moderate, severe and very severe depression in the oldest group (61+ years), amounting to 42.50%.

Short Form Health Survey (SF-36)

Due to missing items, the SF-36 questionnaire was analysed for a group of 124 patients, 83 with NP and 41 with NoP. The NP group obtained statistically significant ($p < 0.05$) lower scores than the NoP group in all domains of the SF-36, thus indicating the poorest health status and significant impairment of quality of life. The results are shown in Figure 1A. The NP group was also analysed in all subscales by gender, place of residence, and age. There were no statistically significant differences ($p < 0.05$) between genders or between places of residence. However, statistically significantly better quality of life in terms of physical function was demonstrated in the group of respondents aged 21–40 compared to the groups aged 41–60 and 61+ (Fig. 1B).

Cronbach's alpha (α) coefficient and ROC

To analyse the internal consistency of the scale, Cronbach's α was calculated. The Cronbach's α value for the entire scale was 0.76, and ranged from 0.52 to 0.87 when the value of one of three subscales was suppressed.

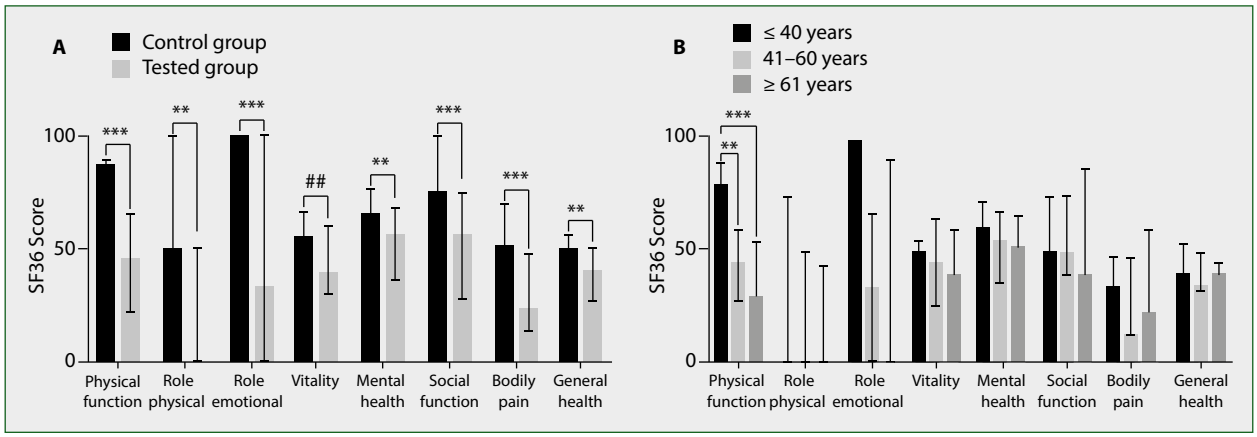

Figure 1. Short Form Health Survey (SF-36) score, median with interquartile range (IQR). **A.** Results for whole group divided into studied group — NP group (83 subjects) and control group — NoP group (41 subjects). Mann-Whitney U test; ** $p < 0.01$; *** $p < 0.001$ and student's t-test for independent samples; ## $p < 0.01$; **B.** Studied group (NP group) divided into groups according to age, post hoc Dunn's multiple comparisons test; ** $p < 0.01$; *** $p < 0.001$

When the repeatability of the questionnaire was assessed using the ICC, reliability was 0.631 (with 95% CI) which indicated moderate reliability [28]. Predictive validity was assessed based on ROC curves for which the area under the curve (AUC) was calculated. The AUC was 0.94, which means very good diagnostic power of the test. The cut-off diagnostic value was determined based on sensitivity, specificity, and Youden's index, corresponding to different total scores. The ROC curve analysis, as the best cut-off value distinguishing NP from NoP, showed a result of 0.481 (Fig. 2), which gives a sensitivity of 90.0% and a specificity of 88.0%.

Correlations between NPQ-SF-PL and various scales used in this study

The Spearman's rank correlation coefficient (R) was estimated separately for the NP and NoP groups ($p < 0.001$). For the NPQ-SF-PL NP group, a moderate correlation with the S-LANSS and a weak correlation with the NRS was found (R = 0.42 and R = 0.32, respectively). The NoP scores revealed a statistically significant moderate correlation with the S-LANSS (R = 0.50). The results are presented in Supplementary material Table 1.

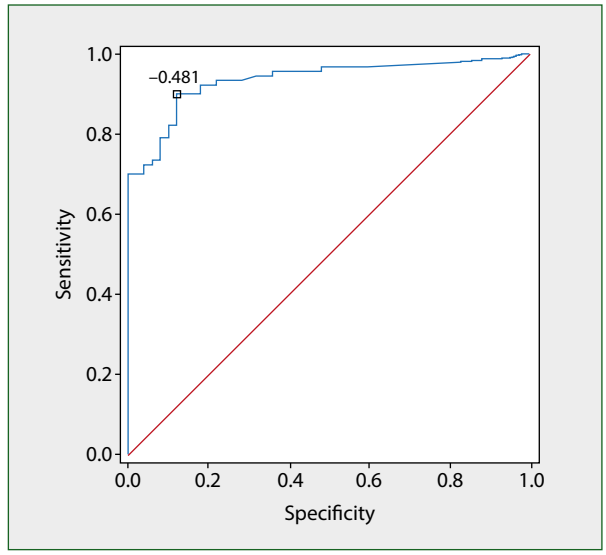

Figure 2. Receiver operating characteristic (ROC) curve for NPQ-SF-PL

Discussion

The present research paper reports on the validation and cross-cultural adaptation of the NPQ-SF to confirm that this tool is an acceptable and psychometrically satisfactory measure of data collection, especially as a screening tool, in Polish patients with chronic neuropathic conditions. The type of neuropathy was assessed by symptoms, clinical examination, and detection tools such as nerve conduction studies, imaging studies and laboratory investigations.

The reliability of the questionnaire was assessed using internal consistency, which assesses both the homogeneity of the test and the degree of correlation between the scale items [24]. The analysis showed appropriate Cronbach's α values for the entire questionnaire, even if individual items scored in the range of 0.52–0.87. The Cronbach's α value for this Polish version was higher than for other validation studies [8, 15, 29]. Other studies' low α values may be related to many reasons including a small number of items or a short test length, poorly related items, or items measuring heterogeneous constructs [29, 30].

The stability of the questionnaire over time was assessed using test-retest reliability. The reliability of the ICC was

moderate and lower than in other studies [8, 15], but these results are probably associated with the earlier re-testing time of the remaining questionnaires. Additionally, the original versions of the NPQ and NPQ-SF did not examine test-retest reliability [12, 13]. A good correlation as obtained between the NPQ-SF and S-LANSS was expected due to the existence of common verbal descriptions such as numbness, increased pain due to touch, and tingling pain. There have been few articles comparing questionnaires. Similar to our study, Spearman's rank correlation was used by Abolkhair et al. [29]. Their results indicated a moderate correlation between NPQ-SF and S-LANSS total scores, as well as a fair correlation between the NRS score and the NPQ-SF total score. Yurdakul et al. [8], using the Pearson's correlation test, provided a moderate correlation between the NPQ-SF and the NRS, as well as a high correlation between the NPQ-SF and LANSS total scores. Using the same Pearson's correlation test, Terkawi et al. [15] found that NPQ-SF items and total score were moderately-to-strongly associated with S-LANSS. Our study also included patients with mixed pain conditions, which could have influenced the results. These conditions are still poorly defined, and clinically manifest as a combination of various pain components which act simultaneously, concurrently and/or overlap to cause pain in the same area of the body [31]. The diagnosis of mixed pain is currently based on clinical assessment following a detailed history and physical examination, rather than a formal confirmation in the absence of diagnostic criteria or screening tests. Many studies have excluded patients with mixed pain conditions from analysis, and studies including these patients have not yielded consistent results regarding changes in specificity and/or sensitivity, limiting the generalisability of the results. However, it is acceptable to use validated screening tools to detect the presence of the NP component [32, 33].

With the exception of place of residence, the demographic data obtained is consistent with previously published results [11, 34–36]. This can be explained by the high references of our centre and the fact that patients from suburban areas are primarily referred to district hospitals. A higher neuropathic ChP prevalence was observed in women and in middle-aged patients, peaking at age 50–64. Additional non-genetic components contributing to this ailment include physical work and social deprivation [11, 37]. In the assessment of pain management, an increasingly important role is attributed to quality of life, everyday functioning and pain-related psychological factors, rather than just to the intensity of pain itself, and therefore these factors are increasingly being taken into account [38]. Nevertheless, patients with NP report higher pain intensity compared to patients with different types of pain, and exacerbations occur without obvious precipitatory factors [34, 39, 40]. A study conducted in patients with peripheral neuropathic (PNP) conditions as the primary diagnosis has shown that SF-36 is a sensitive indicator of ChP. Compared to the general population, patients with PNP had statistically significant lower results. Lower scores on physical function and bodily pain were also found in the non-working PNP group, so these may refer to work ability [41]. Also, reduced scores in all SF-36 domains were observed in patients with chronic NP identified by the S-LANSS questionnaire compared to the chronic non-NP group and the group without ChP. This indicates severely impaired functioning in patients with NP on every measured dimension of overall health, even when compared to patients with other types of ChP. Domains such as physical function, role physical (i.e. role limitations due to physical health problems), bodily pain, and role emotional (i.e. role limitations due to personal or emotional problems), were the most strongly associated with chronic NP [42]. This decline in the scores is consistent with our data, and indicates a reduced quality of life in patients with chronic NP. Another study [43] suggests that as many as 85% of patients with ChP may suffer from depression, and that these patients have a worse prognosis compared to patients diagnosed with ChP only. Moreover, these two diseases are closely related and are able to mutually promote their own progression in severity. Hypothetically, the common pathogenetic factor between ChP and depression may be chronic, subclinical inflammation of the nervous system [44]. According to reports, the coexistence of depression occurs in up to 60% of NP patients; this co-occurrence worsens prognosis and intensifies the severity of pain [45]. Due to the common neuro-mechanism between NP and depression, it appears that the latter may increase the risk of pain or escalate pain sensation, leading to a reduction in quality of life [46], whereas it is ChP that may lead to depression (chronic pain-induced depression) [43]. Some studies also highlight the close relationship between NP, quality of life and depression, especially in long-duration and more severe pain conditions [47]. In the elderly, persistent and untreated pain can lead to social isolation, functional deterioration, poor sleep, and an increased risk of falls. Moreover, the impact of NP on quality of life may be as great as the impact of some other chronic diseases [42, 48]. Epidemiological studies have shown that the prevalence of ChP and depression is higher in women than in men. These differences may be related not only to cultural and social factors, but also to biological factors resulting from gender differences [45, 49].

The results obtained should be interpreted with some caution due to the limitations of our study. The inclusion of patients with mixed pain syndromes in our study may have an impact on the psychometric properties and our conclusions. The usefulness of the questionnaire may also be limited by the fact that the study was conducted only on patients with ChP. It is also undeniable that screening questionnaires are not considered to be a gold diagnostic standard, but rather a guide for further diagnostics. However, their ease of use and availability should encourage doctors of various specialities to use them in practice and, if indicated, to further refer the patient for detailed examinations.

Clinical implications/future directions

To the best of our knowledge, this is the first cross-cultural adaptation of NPQ-SF in a Polish-speaking population. We have demonstrated that the NPQ-SF-PL questionnaire is a valid tool for assessing neuropathic pain in Polish chronic pain patients. The obtained results showed very good psychometric properties and adequate internal consistency. The repeatability of the questionnaire indicated moderate reliability. Also, the correlation with other questionnaires used in the study was moderate or weak. We believe this study will provide physicians with a new tool to evaluate neuropathic pain for clinical and research purposes.

The next step would be to compare the use of the questionnaire in patients with acute NP or to use the self-completion format in epidemiological studies. Growing evidence points to a role of neuroinflammation in the development of both ChP and depression, but robust, large-scale data on this topic is still lacking.

Another interesting issue requiring further research is the use of non-pharmacological therapies to counteract depression, pain and a decline in the quality of life.

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Supplementary material: *The final version of NPQ-SF-PL; Suppl. Table 1. Correlations between NPQ-SF-PL, S-LANSS, NRS and HDRS.*

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